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S. HRG. 103–378

# BIOMEDICAL ETHICS AND U.S. PUBLIC POLICY

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Biomedical Ethics and U.S. Public P...

# HEARING

OF THE

# COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

ON

EXAMINING THE FEDERAL ROLE IN ADDRESSING THE SOCIAL, LEGAL, AND ETHICAL ISSUES RAISED BY ADVANCES IN BIOMEDICAL RESEARCH AND TECHNOLOGY

OCTOBER 14, 1993

Printed for the use of the Committee on Labor and Human Resources

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# BIOMEDICAL ETHICS AND U.S. PUBLIC POLICY

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THURSDAY, OCTOBER 14, 1993

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
*Washington, DC.*

The committee met, pursuant to notice, at 3:00 p.m., in room SD–430, Dirksen Senate Office Building, Senator Edward M. Kennedy (chairman of the committee) presiding.

Present: Senator Kennedy.

## OPENING STATEMENT OF SENATOR KENNEDY

The CHAIRMAN. The committee will come to order.

I apologize to all of our witnesses. Most of them are familiar with the proceedings in this institution. We are late in getting started because of the vote, which was also late in getting started. So we will apologize to them in advance.

Senator Hatfield is on his way. I will make a brief opening comment, and hopefully by that time the Senator will be here.

Today's hearing focuses on the social, legal, and ethical issues raised by advances in biomedical research and technology and the Federal Government's capacity to address these questions.

Last year, Senator Hatfield, Senator DeConcini, and I asked the Office of Technology Assessment to examine past Federal bioethics efforts and to identify the factors that contributed to their success and failure.

Medicine and biomedical research are making dramatic progress in curing disease, increasing longevity, and improving the quality of life. But these medical advances also pose difficult and sometimes unexpected choices.

We are now debating health reform, which is needed in part to reconcile available resources with the unmet needs of large numbers of our people and the simultaneous demand by those who can afford it for the best, latest, and often the most expensive treatment.

Families benefit from new reproductive technologies, but they have also created new dilemmas involving surrogates and adoptions.

We have made extraordinary progress in developing life-sustaining treatments that provide hope for many, but that also raise profound and difficult questions of individual rights and human dignity.

New tests can identify the genetic predisposition to inherited diseases, but they also raise troubling issues of confidentiality.

The challenge of biomedical ethics is not to slow the pace of discovery, but to answer these difficult ethical questions with compassion and expertise.

In the 1970's, the Senate Labor Committee held a series of hearings on the social and ethical dimensions of biomedical research. At that time, concern arose in the wake of disclosures of the mistreatment of patients and research subjects. I remember clearly the hearings that we had on the Ralph girls who were sterilized as a condition for receiving welfare payments. The Tuskegee syphilis study, the involuntary sterilization of young women as a condition for public assistance, and the testing of hallucinogenic drugs by the CIA and the Defense Department on unsuspecting citizens were examples of these past abuses.

In the situation of the syphilis study, the individuals were never notified that there were cures available, and continued to have the disease for years without ever receiving penicillin. Depoprovera was improperly used on women in Tennessee without notifying the women.

Since then, we have become more experienced and capable in confronting these kinds of questions. The discipline of "bioethics" has flourished, matured, and diversified. "Informed consent" is now a central part of our scientific and ethical vocabulary.

However, as medicine and bioethics advance, new questions continue to arise, and new capabilities confront us with unfamiliar choices.

In recent years, Senator Hatfield, who will be here this afternoon, hopefully very soon, has been a leader in the national dialogue on whether we are adequately addressing the fundamental questions raised by the rapid progress of biomedical research. He recently introduced legislation which proposes a new Federal Ethics Advisory Board.

Representatives of the Office of Technology Assessment are also here to testify about OTA's background paper on "Biomedical Ethics in U.S. Public Policy." Their insights will be important to any consideration of a new Federal initiative. I look forward to the presentation of their findings.

Finally, a panel of distinguished bioethics experts will discuss their experiences with past Federal commissions and the appropriate role of Government in contributing to the resolution of complex bioethical challenges.

We will start with Roger Herdman, the Director of the Office of Technology Assessment, and Robyn Nishimi is OTA project director for the "Biomedical Ethics in U.S. Public Policy" background paper. I would ask if they would understand that if Senator Hatfield arrives, we will adjust to his schedule.

Dr. HERDMAN. We can interrupt at any time, Mr. Chairman.

The CHAIRMAN. We are delighted to have Roger Herdman here as the Director of OTA. All of us are enormously impressed by the good work of OTA under Dr. Herdman's leadership, and the collection of some enormously talented individuals who work very effectively in providing Congress with important information which hopefully we can utilize and perform our responsibilities with better balanced judgment. We are delighted to have you here.

## STATEMENTS OF DR. ROGER C. HERDMAN, DIRECTOR, OFFICE OF TECHNOLOGY ASSESSMENT, CONGRESS OF THE UNITED STATES, WASHINGTON, DC; AND ROBYN Y. NISHIMI, PROJECT DIRECTOR, OFFICE OF TECHNOLOGY ASSESSMENT, CONGRESS OF THE UNITED STATES, WASHINGTON, DC

Dr. HERDMAN. Thank you, Mr. Chairman.

Mr. Chairman, it is a pleasure to appear before you this afternoon to release the Office of Technology Assessment's background paper, "Biomedical Ethics in U.S. Public Policy," which was jointly requested by you, Senator Hatfield, and Senator DeConcini. In preparing this document, we were assisted in our efforts by the deliberations of eminent bioethicists at a workshop chaired by Dr. David Blumenthal and attended by Senator Hatfield, and by the contributions and reviews of over 100 individuals from 36 countries.

The OTA report is intended to provide Congress with information about the form a new Federal bioethics body could take and what factors might increase effective functioning of that commission. My remarks will be brief, as I am accompanied by Dr. Robyn Nishimi, who directed the OTA study, and she will expand on the details of the report. At this time, I would also like to acknowledge the contributions of Ms. Ellen Goode, who assisted on the overall report and oversaw the appendix on international bioethics initiatives.

Mr. Chairman, over the past 2 decades, Congress has exhibited an enduring interest in bioethics. I know I need not remind you, as a consistent sponsor of that interest, that we continue to pay the ethical and economic costs of not being sufficiently vigilant about the societal ramifications of biological research and medical technology. For example, this year, as in years past, Congress will appropriate funds for the ongoing medical care of survivors of the Tuskegee syphilis study—as you mentioned, Mr. Chairman, an ignoble incident in the history of U.S. research, whereby more than 400 African American men infected with syphilis were denied penicillin so the U.S. Public Health Service could follow the long-term effects of that disease. Let no one doubt that the compensation is appropriate; it should also serve as an ever present reminder to us all about the important role of bioethics in U.S. governance.

In a statement that applies as well now as it did 20 years ago, you noted at a congressional hearing, and I quote, "We have all been touched by, and have all profited from, the fruits of biomedical research. The new developments in biomedical research hold great promise for significantly improving the health of the American people. But we have also seen that this new technology of man raises profound ethical questions—questions which our society must address if we are to apply the new technologies wisely and constructively. In the next decades, scientists will place even more powerful tools in our hands. We will, as a society, have to be ready to answer many questions."

Today, OTA believes that as the frontiers of biomedical research and medical technology continue to advance, it remains essential for policymakers and the public to understand the ethical implications of the innovations that flow from laboratories and research hospitals to the doctor's office, the clinic, and the pharmacy.

That ends my statement, Mr. Chairman. Now I would like to turn the podium to Dr. Nishimi.

Ms. NISHIMI. Thank you.

Mr. Chairman, OTA appreciates the opportunity to appear before you today to discuss our background paper, "Biomedical Ethics in U.S. Public Policy." I will summarize my remarks in the interest of time.

As you requested, OTA reviewed the history of the National Committee for the Protection of Human Subjects of Biomedical and Behavioral Research, the Ethics Advisory Board, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, and the Biomedical Ethics Advisory Committee. We also examined the initiatives of New York State and New Jersey and summarized bioethics activities in over 50 countries or multinational organizations.

The CHAIRMAN. In your report did you find any Federal agencies which developed an ethical board?

Ms. NISHIMI. There have been a few ad hoc panels that we have reviewed in a less thorough fashion that we did describe in the report.

The CHAIRMAN. I see.

Ms. NISHIMI. Although federally funded bioethics entities have disappeared in this country, they have flourished elsewhere. The governments of at least 27 nations on 6 continents have established a national commission of some type or currently have legislation pending to do so.

Mr. Chairman, as you are aware, the Federal Government has been without a formal forum that addresses bioethical ethics for 4 years, and in fact, a fully operational body has not existed for over a decade.

Nevertheless, State, local, and private initiatives have developed. Such a pluralistic approach has advantages over a single national commission. For example, it can foster diversity. Other pitfalls with centralization could include a tendency to lose flexibility in interpretation, diffusion arising from forced consensus, and the potential for capture by political interests.

On the other hand, the diversity in bioethics organizations cannot always succeed in addressing areas that require expansive access to information and expertise. Centralization brings authority to a process that is rarely achieved with decentralization. A Federal effort also can call on greater resources and has nationwide power to gather data, convene meetings, generate relevant analyses, and invite testimony. The process by which OTA's background paper was produced demonstrates this value: Though allocated a limited budget and a short time frame, our project gathered responses from around the world that were rapid and impressive because it was an effort on behalf of the U.S. Congress.

Of the four entities that OTA reviewed, we found general consensus that the first three—the National Commission, the President's Commission, and the EAB—were viewed——

The CHAIRMAN. Ms. Nishimi, would you just hold up?

Ms. NISHIMI. Sure.

The CHAIRMAN. Senator Hatfield, we have indicated this to others. I told them that we had the votes, and we are all arriving at different times. We have apologized to our witnesses, but we know that you have a pressing schedule as well. They look forward to hearing from you.

We will ask in the record that Senator Hatfield's statement appear as the initial statement and then the following panel statements appear uninterrupted.

## STATEMENT OF HON. MARK O. HATFIELD, A U.S. SENATOR FROM THE STATE OF OREGON

Senator Hatfield. Thank you, Mr. Chairman. I thank you very much for that, and I apologize for the interruption here. I do appreciate the opportunity to appear before you today, and I would like to submit the entire statement as if given. And conserving what is left of my voice, I will try to summarize.

First of all, Mr. Chairman, I would like to take note that amongst your witnesses today is Dr. Susan Tolle, who is a distinguished director of the Center for Ethics in Health Care at the Oregon Health Sciences University in Portland, OR. She has certainly been recognized as a national leader in health care and biomedical research. Her leadership was absolutely essential in the developing of the Oregon plan, which has become quite well known, wherein there are tough decisions involving ethics and values and many other factors in developing a priority listing of the 709 medical procedures that would be available for expanding Oregon's Medicaid program and health care program for primary care for all of our citizens.

As you know, Mr. Chairman, the OTA has expended a great deal of time in preparing their report here today, and that came about as a result of you, Mr. Chairman, and Senator DeConcini and myself in requesting this report from OTA to sharpen the issue of today's discussion and looking forward, hopefully, to some kind of a resolution of this very complex issue.

I think in all of this that we are trying to maintain what we might call the human face—the human face—as a center of all of our decisionmaking with the social, economic, and environmental problems of today. One of my highest priorities as a legislator is seeing an increased emphasis placed on resolving human afflictions. I have called for a reordering of our national research priorities from activities focused on increasing the capacity and efficiency of destroying life to that of enhancing and preserving life.

So my interest in this issue has taken form in many different directions, and especially as it was focused in the field of genetic engineering. The Chair has certainly been an important part of this because when I offered the amendment on the floor during one of the authorizing bills, it was indicated then that perhaps a hearing of this kind by both this committee and the Labor Committee be held, which is now taking place.

Mr. Chairman, if I were to summarize, I suppose, in one or two sentences, it would be that I am deeply troubled by the patenting issue, first of all, in which we are now engaged in requests for patenting of human life, of animal life, or its components. And I just do not think the Patent Office as constituted over 200 years ago is equipped to undertake that kind of activity and decisionmaking based upon the normal role of the Patent Office.

I need not go back and recite the history of the Harvard mouse and other animal patenting programs that called for patenting because they have certainly been at least well publicized.

I recall also when Dr. David Baltimore made his famous interview with U.S. News & World Report a number of years ago in which he was discussing genetic engineering, patenting, the possibilities, and his statement was to the effect that scientists have only one of two options: they can cease research entirely, or they can find what they find, discover what they discover, and turn it over to society.

Mr. Chairman, that bothered me because, concurrent to that interview, in that same week, Wall Street had one of its fastest sales of stock, and that sale was in a genetic engineering company. One could say that society at that moment was represented by Wall Street, and I am not about ready to turn that type of decisionmaking over to the commercial centers of this country.

The biotechnological industry has opposed the proposal, not so explicitly, though I understand the reasons, but certainly enough to understand that there could be economic concerns expressed in their opposition.

When the National Institutes of Health sought to have 2,000 gene sequences patented from the human brain DNA, I thought that raised profound ethical questions. And it is very interesting that today many of the ethical questions in the practice of medicine are being considered, but there is no consistency of where and who is doing the considering.

If you take Baby "M," that is a contract law that is being considered. If you take gene patenting, that is the Patent Office. If you take Dr. Kevorkian, that is a criminal law matter.

None of these really, in effect, represents the comprehensiveness that I think should be applied to some of these puzzling questions.

We had a convocation a number of years ago by the clergy of New York who had Hebrew, Catholic, and Protestant clergymen represented. One of the major resolutions considered was that we should halt this kind of research until we had some kind of way to establish an ethical and a moral dimension to what we are discovering.

Dr. Vannevar Bush many years ago in his own book, "Modern Arms and Free Men," called to the public's attention that scientists oftentimes in the laboratory do not have a clear understanding of the kind of world in which they are placing their inventions or their discoveries. He called for a better bridge between the sociological, historic, the human entities, all the other disciplines, and the pure science disciplines.

Now, first of all, I am not opposed to research. In fact, I stand very foursquare behind continued medical research. Senator Harkin and I have introduced legislation calling for a medical research trust fund. The Republican program for comprehensive health care incorporates that. Senator Harkin is working with the administration to make sure that the administration's ultimate program will include health care research, medical research, which after all is the ultimate cost containment in any kind of medical program—

that is, cure. So I do not believe that one could say that to be concerned about this means one is anti-scientific or anti-research.

Dr. Tolle will express also the momentum behind euthanasia initiatives in my State. As you recall, a euthanasia initiative came very close both in the State of Washington and the State of California in the last election cycle. I do not think the ballot box is a place where such ethical matters should be determined either. I think that is certainly a component in our consideration of how to handle matters of this complexity. I am not sure that the criminal court is going to finalize Dr. Kevorkian's role in assisted suicide.

But all of these things do, in my view, call for a very carefully crafted commission to have as a permanent part of our country a national review, not only looking at the legal implications—how much pain-killing medicine may a doctor administer knowing that the quantity may be a way to reduce or eliminate pain but be excessive to the life preservation or the life span? In other words, are you trading a few less months of life to reduce pain?

You have legal implications in this. You have ethical implications. You have sociological implications. You have philosophical and theological implications. And it all calls for, I think, some kind of a national attention. So I hope, Mr. Chairman, that out of the OTA report, which I have had an opportunity to read the summary of such, and to gain further support out of the witnesses that you have called here today, that whether my bill calling for such a national commission is the ultimate answer or not—I am not locked into concrete on that subject—I do hope that out of this committee can come some kind of a mechanism where we can focus on these many complexities that are confronting us more and more, day by day, in terms of health, in terms of life, in terms of how we discover new ways of preserving life, enhancing life, and at the same time recognizing that some of this will be in the field of science yet to be finally determined or in the process of discovery. I think we have to get ahead of the curve on this.

Mr. Chairman, I will close my comments with the request that a series of articles from Health News and from other medical and science magazines relating to this subject matter might be incorporated in the record.

The CHAIRMAN. They will be so included.

[The prepared statement of Senator Hatfield and articles referred to follow:]

### PREPARED STATEMENT OF SENATOR HATFIELD

Thank you, Mr. Chairman and members of the committee, for conducting this hearing today and allowing me to contribute to what expect will be fascinating dialogue on the subject of bioethics.

—You have gathered together some of the most thoughtful professionals in the nation to help us put these issues into perspective. Their work to date and their testimony today will assist us as we determine how best to ensure that the many ethical dilemmas facing this Nation are addressed in a responsible manner.

—I would like to extend a special welcome to one of the witnesses appearing today. Dr. Susan Tolle, the distinguished director of the Center for Ethics in Health Care at Oregon Health Sciences University in Portland, Oregon. The State of Oregon has been a national leader in health care and biomedical research. This leadership has required a vast number of decisions, many with profound ethical implications, including our "Oregon Plan" for health care reform. Dr. Tolle has been involved in many aspects of these efforts and can speak authoritatively about the lack of thoughtful ethical parameters in many areas of health care. I welcome her.

—Let me also thank the Office of Technology Assessment staff for their fine work in preparing the report to be issued today. This report dates back to just over a year ago when I joined with you, Mr. Chairman, and Senator DeConcini, in requesting the report that OTA is prepared to issue today. OTA's work has sharpened the issues for today's discussion and I look forward to their testimony.

Mr. Chairman, I believe one of the biggest challenges facing public officials today is to keep the human factor—the human race—firmly in mind when we act on the significant social, economic and environmental problems of today. One of my highest priorities as a legislator is seeing an increased emphasis placed on resolving human afflictions. I have called for a reordering of our Nation's research priorities from activities focused on destroying life to those which enhance life.

—My involvement in this issue began as the result of my concerns about the direction of genetic engineering. With its potential to enhance life, also see a potential to trample on the human factor and confuse the idea that human life is sacred.

—Let me state at the outset that I am not an enemy of biotechnology. To the contrary, I am a strong supporter of medical and technological advances, but not without some regard to the ethical issues encompassed in their development. This is particularly true when special status is sought in the form of Federal Government patents.

—Genetic engineers are assuming a new role in our evolutionary scheme. They are using their new-found abilities to alter the blueprint of life, to apply cold mathematical values such as efficiency, utility and predictability to the manipulation of life forms.

—Scientists are currently inserting human genes into animals, and beginning the process of altering the genes of humans. Many predict that within a few decades, our biotechnologists could assume the roles of creator and designer of the human, plant and animal community.

—About a decade ago, the U.S. Patent and Trademark Office began considering patent requests on genetically altered animals.

—These animals, primarily mice, had been genetically altered in a way that made them particularly useful in cancer research. Those responsible for creating these new creatures sought patent protection for their inventions. This prompted a vigorous public debate over the ethical questions raised by stamping a patent number on a living creature.

—I participated in this debate and introduced legislation to place a moratorium on patenting, pending proper consideration of the ethical considerations involved in patenting. Members of the Senate have not embraced the legislation, believe largely because few of us are truly qualified to deal with the complex legal, scientific and ethical issues raised. And because these issues are very difficult to resolve, especially in the political arena.

—In 1991, the issue of patenting life became more pressing when the National Institutes of Health sought patents on over 2,000 gene sequences from human brain DNA. This request raised profound new ethical questions, again to be addressed by the Patent Office, aided only by the centuries old patent law. Our world trading partners also expressed their concern at this unprecedented maneuver. The NIH patent requests are now pending at the Patent Office.

The lack of interest in these issues puzzles me greatly. But in reviewing the issue, I became aware of many other issues of similar difficulty that were also going unaddressed. Many have asserted that advances in science have outdistanced the legal and ethical parameters that we have in place to deal with them. One need only glance at the newspaper today to find examples of unresolved, but profoundly serious ethical questions.

—This committee is aware of the recently debated Oregon Health Plan. This plan is controversial. Many of the provisions of the plan required the drafters to make ethical judgments about limiting public payment for services in order to increase access to basic health care services to all Oregonians below the Federal poverty level. Oregon's bravery is rare, however, and was only possible due to significant public involvement in developing community values.

—Certainly, Oregon's experience can be used as a model as we begin the debate on national health care reform proposals.

—Euthanasia and even what many would consider compassionate care for the dying is often handled under State criminal law statutes, where there is little room for ethical considerations in making black and white determinations of law.

—Questions of access to organs for transplantation, research on human beings, genetic therapy and genetic privacy and a host of others considerations deserve all the attention we can give them. It is our responsibility to ensure that these issues are raised and dealt with.

It is not my purpose to question the potential benefits that these technological advances could bring to the human race. Cures for diseases such as alzheimers, diabetes, miracle drugs, an end to human infertility are predicted.

—Indeed, I am working to secure more resources for biomedical research through a National Medical Research Trust Fund as a centerpiece of national health care reform.

—History has taught us, however, that the benefits of most new technological revolutions are accompanied by costs to society. The more adept the technology is at harnessing the forces of nature, the greater the potential for disturbing the balance of nature. Society's experience with both the nuclear and petrochemical revolutions confirm this truism.

—Our Nation and the world remain utterly dependent on finite fossil fuel resources. Assuring access to these resources will continue to lead oil-dependent nations to use military force to secure that access. Moreover, each day Americans suffer the adverse health consequences of increasing fossil fuel use.

Obviously, I am not arguing that we should eliminate the automobile, but recognize that society continues to pay a high price for its emergence.

—Similarly, I am not arguing against advances in biotechnology or other advancing areas of science. I am simply saying that society must carefully evaluate new products and the implications of new frontiers. Although it is difficult to legislate in these complex areas, Congress——as the elected representatives of the people—must play a role in seeing that these important problems are addressed.

—A few years ago, I had a chance to visit with a prominent scientist about the ethical issues raised by genetic engineering. He told me that science has only two options when dealing with this new technology: one is to stop research altogether and the other is to discover what science can achieve and then turn the results over to society to decide how it is to be used.

—If that is the role of the scientist, then we must ensure that the additional considerations are raised and addressed. It is our responsibility to act on behalf of society.

The OTA report soon to be presented to this committee reviews prior Federal efforts in the area of bioethics. Mr. Chairman, I know that you have a long history of involvement and accomplishments in this area.

—There is a great deal to be learned from looking at our successes and failures with federal bodies to review biomedical ethics questions and the OTA report does an excellent job of focusing the issue.

—I have introduced legislation to establish a standing ethics advisory board within the Department of Health and Human Services. It is my hope, Mr. Chairman, that you will review the merits of this legislation in light of the testimony you hear today, as well as the OTA report.

—The debate should not end here. Congress should ensure that there exists a body where these difficult ethical issues can be aired out thoroughly.

Thank you for allowing me to contribute to this important discussion. I look forward to further activity by the committee in this area.

OCT 13 '93 05:25PM LOC CRS

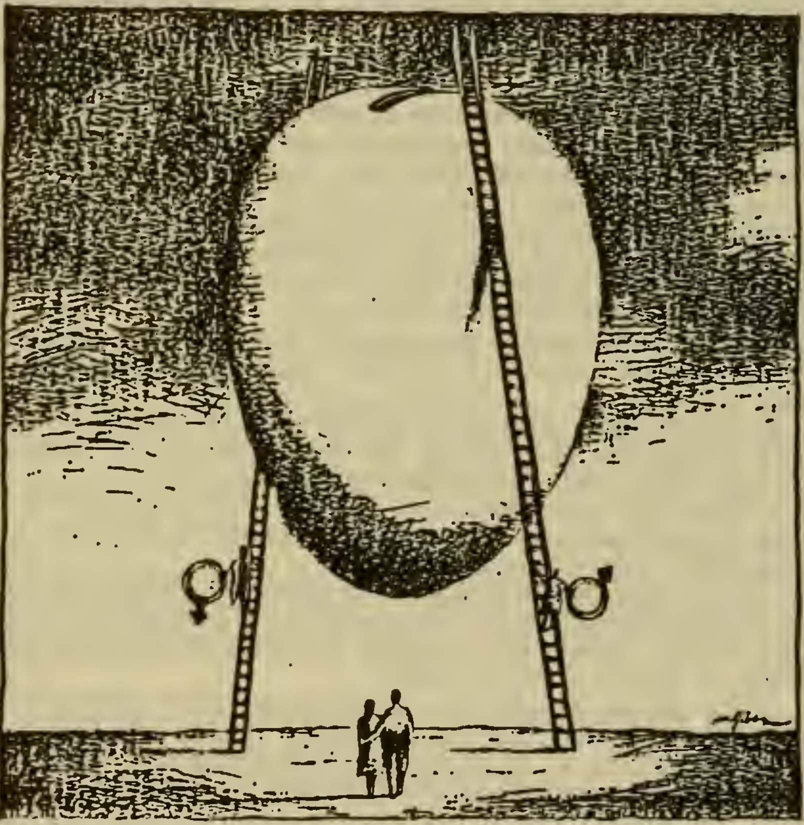
**ANALYSIS**

LEGAL TIMES. W.1K-8 8-23-93 p.2

# Sex Preselection: Making Babies to Order

## Modern technology now enables parents to select the gender of their child or to skew significantly the probability of bearing a child of the desired sex. This raises a host of ethical, social, religious, and legal issues.

BY OWEN D. JONES



Humans have endeavored for millennia to determine the sex of their children. The fanciful, cruel, and sometimes bizarre methods that creative minds have designed stand as a testament to the breadth and strength of the desire to do so. Only recently, however, have technologies afforded a real opportunity either to select the sex of a child (as by in vitro embryo-screening, followed by selective implantation) or to skew significantly the probability of bearing a child of the desired sex (as by sperm separation, followed by artificial insemination).

As sex selection moves from myth to technological reality, many have begun debating the ethical, social, religious, and legal implications. Sex-selective abortions became a hot issue in the 1990 Democratic gubernatorial primary in California, for example, and the British Medical Association recently declared it unethical for doctors to provide preconceptive sex selection for reasons not deemed medically compelling. Unfortunately, such issues have often been framed by seemingly irreconcilable opponents—one camp advocating outright prohibition and the other advocating governmental laissez-faire. Although little progress has been made in mediating the conflict, careful scrutiny of competing arguments, informed by the long history of sex selection, suggests that there is far more room for constructive compromise than previously thought.

The prevalent method of post-conceptive sex selection was historically—and in some places remains—infanticide. The inefficiency of this inhumane method has always been obvious, however, since it eliminates the unwanted without providing the wanted.

Early methods of preconceptive sex selection—which, in contrast to post-conceptive selection, seemed to afford greater latitude to human ingenuity—may be roughly sorted into biologic and symbolic techniques.

Preconceptive biologic methods, prescribing either elaborate behavior during intercourse or specific variations in the female diet, attempted to capitalize upon supposed correlations between offspring's sex and, for example, a parent's position at orgasm, the timing of male and female orgasm, the side of the body contributing sperm or egg, the consumption of items ranging from lion's blood to sugar, or the vigor of copulation. Not as long ago as we might hope, people even recommended that husbands rape their wives to produce a male child—on the theory that the more "male" a man acted, the greater the likelihood of fathering a boy.

Preconceptive symbolic techniques, depending more on mystical than on supposed biological influences, involved everything from cross-dressing before intercourse to carrying an ax into bed. None of these techniques, as one may imagine, has proved dependable.

But then, in 1920, the X and Y sex chromosomes were discovered, and everything changed. With the increased understanding of biological sex determination, and the rapid advance of technologies enabling isolation and manipulation of sperm, egg, and embryo, researchers began to develop more reliable methods of selecting a child's sex. Modern post-conceptive techniques include the in vitro method of separating developing embryos by sex (based upon genetic analysis) and implanting an appropriate embryo in the womb, and several in vivo methods, which require "sexing" a fetus (by amniocentesis, chorionic villi sampling, or ultrasound) and aborting one of the "wrong" sex.

Modern preconceptive techniques increasingly include the separation of X-bearing from Y-bearing sperm, followed by artificial insemination of a woman with an "enriched" (that is, X-biased or Y-biased) quantity of sperm. While sperm may be separated, to some extent, on the basis of size, weight, and perhaps electrical charge, the most successful method capitalizes on the different average swimming speeds of X-bearing and Y-bearing sperm: The sperm are raced through successive layers of the viscous protein albumin. Y-bearing sperm swim faster on average—although they are apparently more vulnerable than X-bearing sperm to variations in, for example, cervical mucous acidity.

While the latter method is not perfect, the most recent data indicate that it can skew the probability of conceiving a boy or girl from roughly 50 percent to approximately 75 percent. If those employing the technique all selected for the same sex, therefore, the gender ratio for selected offspring could be skewed from 1:1 to 3:1.

The long history of efforts to influence sex suggests a ready-made demand for this growing supply of technologically facilitated sex-choice procedures. Moreover, surveys demonstrate that the willingness to pursue and to supply such procedures has increased sharply over the last 15 years. Although the difficulty in discerning the reasons why a woman seeks an abortion makes it impossible to know the number of women employing this post-conceptive technique to choose their offspring's sex, the presence of more than 50 clinics in the United States offering sperm separation for sex-selection purposes indicates that sex preferences are, in fact, being actualized. For those troubled by

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the image of parents choosing their offspring's sex, the growing market in such procedures bodes ill.

While to some the existence of parental preferences may be troubling in itself, others find it even more so because of the substantial evidence that sex preferences are dramatically unbalanced. The preference for male children in foreign countries is widely known. A 1982 survey of six Indian hospitals, for example, revealed that of 8,000 abortions performed after amniocentesis, 7,997 were of female fetuses. (And the substantial gender-ratio skew in the Indian population has been the subject of press attention for some time.) Recent reports indicate that, partly due to post-ultrasound abortions of female fetuses, the sex ratio of newborn children in China has skewed from 105 boys-to-100 girls to nearly 120 boys-to-100 girls. These dramatic preferences have been attributed, in part, to such cultural and economic factors as differential lifetime earnings, the prevalence of the dowry, and strict patrilineage.

Yet American society, too, reflects strong gender preferences. Dozens of studies, spanning the 1930s to the 1980s, have revealed a consistent preference for a male child (in a one-child context) or for a male as the first child (in a multi-child context). The evidence suggests that these preferences vary little across lines drawn by race, religion, class, gender, or educational pedigree.

What shall we do with this information? Regardless of one's personal views on the legitimacy of having or actualizing gender preferences, it is clear that there are a wide variety of reasons why parents may prefer a boy to a girl, or vice versa. Parents may, for example, wish to satisfy sequential or compositional goals—that is, to bear the sexes in a given order (e.g., boy first, then girl), or to bear the sexes in a certain proportion (e.g., two girls and two boys).

Undoubtedly, some such preferences may be traced to irrational gender stereotypes. In many contexts, abilities and interests appear to be a function more of nurture than of nature. On the other hand, some parental preferences may be "rational" (albeit regrettably so) in the technical sense that they can be traced to practical considerations that reflect the existing differential treatment of the sexes. Parents seeking financial support in old age, for example, will consider the sex of a child relevant so long as men and women have different lifetime earning potentials. Sex preferences often also reflect the fact that more than 400 diseases are genetically sex-linked. Parents at risk of bearing male hemophiliacs, for example, may prefer to have girls.

Yet recognizing parental, even societal, advantages to bearing a boy or a girl in a specific context is quite a different thing from determining that sex selection is normatively good. Many have argued that the process of creation should remain the province of divine will or chance—rather than of human meddling. Consequently, some believe that sex selection is inherently evil, violating basic principles of fairness, equal love, and parenthood. Moral arguments that sex selection is unnatural, is playing God, and is fundamentally and invidiously sexist have already inspired considerable debate.

Other critics believe that the most objectionable aspect of sex selection lies not in its fundamental nature, but rather in the consequences of how it can be used. The intimate relationship between sex-biased opportunities and sex selection creates significant and problematic dynamics. Differential opportunity yields unbalanced sex preferences and contributes to the willingness to select sex. Yet actualizing sex preferences through sex selection may then reinforce social biases and exacerbate undesirable discrimination. As long as there is widespread preference for males, certain critics maintain, sex selection will also skew the sex ratio in favor of males, cause women to be confined to subordinate roles, and yield enforced male celibacy, greater recourse to prostitution, and increased male unhappiness consequent to decreased access to mates. Children, too, may be adversely affected by the psychological burdens of being the "superchild" or, perhaps worse, the result of a failed attempt to select for the opposite gender.

These potential externalities (to use the economists' term) indicate that people pursuing sex selection may not themselves bear the full costs of the activity, which buttresses the argument for government intervention.

With increased public discourse in the social science, ethical, and medical literature, positions on sex selection have become increasingly polarized, with diminishing numbers of neutral observers. While some have argued eloquently for nearly blanket reproductive freedom, others have begun widespread calls for the outright prohibition of sex selection through criminal and civil penalties. Pennsylvania and Illinois, for example, have passed legislation providing criminal and civil penalties for sex-selection abortions. And although attention to sex selection has been largely catalyzed by the broader abortion conflict, the legal and policy arguments for and against prohibition of sex-selection abortion, a postconceptive method, extend almost uniformly to the preconceptive context as well. In the wake of the Supreme Court's 1992 abortion decision in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, which to some extent quiets the struggle over the right to abortion generally, preconceptive sex selection may become a new battlefield.

Women's groups, many of which oppose government intrusion upon "reproductive liberty," have found sex selection most troublesome. On the one hand, prohibition of sex selection seems to compromise hard-won freedoms. On the other hand, there is a very real concern that unrestricted sex selection could skew the sex ratio in favor of males—yielding further disenfranchisement of females. Thus, theory may be strained by the weight of consequence.

But a government may prudently pursue policy approaches other than those espoused by the antagonistic prohibitionists and non-interventionists. Close scrutiny suggests that the supporters of these policy extremes are not all extremists themselves. Dividing them by the way they think (the process by which they reach their conclusion), rather than by what they think (the conclusion they actually reach), reveals two distinct but previously huddled groups: absolutists and consequentialists. Absolutists take the position that sex selection is either fundamentally wrong or fundamentally within that sphere of reproductive activities over which a government's influence must be severely limited. Consequentialists, on the other hand, are primarily concerned with effects. They believe that unrestricted sex selection will adversely skew the gender ratio, for example, or that restricting sex selection will necessarily impinge on other reproductive activities or individual liberties.

While the absolutists may be separated by a chasm too wide to cross, prohibitionist consequentialists and non-interventionist consequentialists do share common ground. Both, at base, are concerned about controlling the effects of government policy on sex selection. Yet, even if one were to grant the consequentialists all of their premises, their arguments for the policy extremes of prohibition or non-intervention are seriously undermined by the potential for alleviating regulatory strategies.

Creative governmental policy makers could design programs that would accommodate the consequentialist concerns. For example, if consequentialists fear that sex predetermination will result in a greater number of males than females being born, then appropriate policy-makers could establish a threshold level of gender ratio skew, beneath which the issue would simply be ignored. Should that threshold be transgressed, the government could keep sex selection within acceptable quantitative limits with licensure, taxes, permits, or a combination of other traditional regulatory tools. While each of these may yield new issues of concern, such as those attendant to unequal wealth distribution, the difficulty of mediating new conflicts should not alone justify acquiescence in a single, uncompromising legal or political position.

One may hope that efforts to dispel irrational gender-based stereotypes and provide equal opportunities to both sexes will diminish or eradicate sex preferences. Yet the fears such preferences currently inspire, and the cycle of extremism that strong fears create, should be addressed in a deliberate fashion.

It is unclear whether many of the results of sex selection that consequentialists posit would occur even if sex selection were completely uncontrolled. Even if they did develop, however, manifested consequences do not alone justify blanket prohibition. At best, they suggest regulation.

*Owen D. Jones is an associate at D.C.'s Covington & Burling, where he specializes in law affecting medical devices, drugs, and reproductive technologies. He is also the author of "Sex Selection: The Regulation of Technology Enabling the Predetermination of a Child's Gender,"* 6 Harvard Journal of Law & Technology 1 *(1992), and the forthcoming "Reproductive Autonomy and Evolutionary Biology: A Regulatory Framework for Trait Selection Technologies,"* American Journal of Law and Medicine *(Fall 1993). The views expressed herein are those of the author, and do not represent the position of the firm or of any client.*

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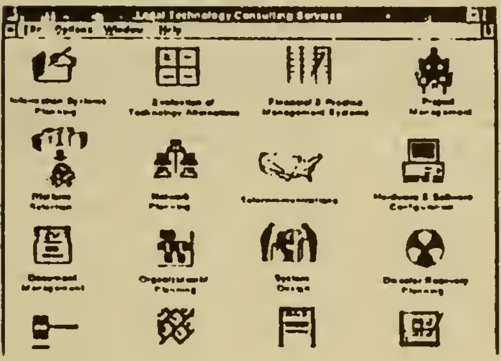

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# Who Lives, Who Dies — and Who Pays?

## Separation of Siamese Twins Highlights Ethical Impact of Medical Choices

**By Richard Saltus**
Boston Globe

The willingness of doctors in Philadelphia to operate on Siamese twins Angela and Amy Lakeberg even though their parents were unable to pay the bill, which is sure to reach six figures, shows American medicine at its best, a leading Boston pediatric surgeon said.

But a prominent bio-ethicist, contrasting the huge expenditure with the long shot odds of success, said the case symbolizes American health care delivery at its worst.

These conflicting views are being expressed at a pivotal time in the debate over how to reform the U.S. health-care system, and experts say the dramatic attempt to save one of the Lakeberg twins brings important cost issues to a flashpoint.

Hardy Hendren of Children's Hospital in Boston, who has operated on nine sets of "conjoined," or Siamese, twins, said many physicians believe that their main duty is to the patient. "We certainly can't look at a child and say this particular treatment will cost more than some prescribed amount of money, and therefore we won't do it," he said. "Physicians can't be put in the position of making such judgments."

"This was an extraordinary surgical undertaking," Hendren said, and "they did a super job that takes enormous combined skills in surgery and anesthesia and nursing."

The Lakeberg twins, about 2 months old at the time of their surgery, were born joined at the chest and abdomen; they shared one heart, the larger part of which beat in Angela's chest. They were separated in a 5½ hour operation Aug. 20, in which Angela retained the heart and her sister, Amy, was allowed to die.

Angela Lakeberg remained in critical condition this week.

Arthur Caplan, director of the Center for Biomedical Ethics at the University of Minnesota, said the chances of even one of the Lakeberg twins' surviving are too remote to justify the costs.

"Symbolically, cases like this make us believe that the proper expenditure of health care resources is to pursue desperate measures for identified people regardless of the cost," Caplan said.

By "identified people," he meant patients whose cases receive so much publicity that their names and faces become widely known. "We're really good at rescuing identified lives, but horrible at doing things" that may benefit masses of unknown, faceless people, Caplan said.

There have been no survivors among twins born joined at the heart, and doctors at Loyola University Medical Center in suburban Chicago, where Angela and Amy were born, opposed attempting to separate them. They said that Amy would certainly die and that Angela had only a 1 percent chance of survival.

At Children's Hospital of Philadelphia, the care of the Lakeberg twins before the operation, the surgery itself and early postoperative treatment of Angela already has cost $35,000, a hospital spokeswoman said. That sum, she said, does not include doctors' fees, which might be donated.

But if Angela survives for weeks or months, the biggest expenses are still ahead. Basic charges for the intensive care unit are $1,800 a day, a hospital spokeswoman said, but other specialists said that adding the costs of diagnostic tests, lab fees, respiratory therapy and other items could increase the total bill to between $7,500 and $15,000 a day. (The actual cost to the hospital is less, because some portion of the charges represents fixed costs, such as facilities and staff.)

Medicaid in Indiana, where the Lakebergs live, is paying $917 a day, and other contributions are coming from funds established in their hometown and at the hospital, the Philadelphia Children's spokeswoman said. Children's Hospital will pick up the remaining costs, she added.

A highly publicized case of separating conjoined twins involved Benjamin and Patrick Binder, who were born in Ulm, Germany, connected at the head. More than $1 million was spent on that case; a German magazine paid much of the cost in exchange for press rights. The complex surgery was performed in 1987 at Johns Hopkins Children's Center in Baltimore.

Both children survived and returned home but suffered significant neurological impairment. In an interview for a story in The Washington Post earlier this year, Theresia Binder said her son Benjamin at the age of 3 could still only babble like a baby. Patrick is unable to display any facial expression. Medical experts have told her that neither twin will be able to go to school, she said.

Mark Rogers, chief executive officer of Duke University Hospital, was the pediatric expert at Johns Hopkins who helped arrange the surgery for the Binders.

"Concerns about cost are changing so rapidly that I would be much more sensitive about that issue now than I was then," Rogers said. Physicians face an enormous dilemma when they are asked to try to save the life of a child when the odds of success are small and the costs great, he said. "Are they responsible for their patients, or to society?" he asked.

In the view of Caplan, the University of Minnesota bioethicist, therein lies the great defect of the health-care system: There are advocates for the patient, but no advocates for society.

"I think a system that has nobody to say 'no' to a million-to-one shot on an experimental treatment with a million-dollar cost isn't much of a system," he said.

Caplan, who recently returned from a meeting of European bio-ethicists, said they had generally agreed that the operation for the Lakeberg twins would not have been performed in their countries — and that parents would not have expected it.

"Time and again they said, 'We would not allow the desperate needs of a few to distort the provision of basic resources for all,'" Caplan reported.

The equation is not simple, Caplan agreed. "I can't say that if you didn't do this operation, then the 40 percent rate of vaccination in West Philadelphia would be better," he said.

Even if the U.S. system presently lacks a framework for making such decisions, he said, cost-cutting health care reforms may reduce hospitals' ability to provide high-cost services free. "Academic medical centers aren't going to have the same resources," he said. "They are going to be held much more accountable for the money they spend." ■

Conjoined twins Angela and Amy Lakeberg, shown at age 6 weeks, shared one heart before surgeons separated them on Aug. 20. Amy died, and Angela is in critical but stable condition at Philadelphia Children's Hospital.

# Editor's COMMENTS

## Family values part II

Just when we thought we were safe to run our own lives comes a spate of news articles and commentaries blaming divorce for society's woes.

According to these news reports, researchers have discovered that children of single-parent families are poorer and have more behavioral problems than children in two-parent families. Barbara Dafoe Whitehead of the Institute for American Values maintains that children who grow up in single-parent or step-parent families are less successful as adults.

Such findings commonly are reported in conjunction with comments by pundits and professors questioning the right of parents to divorce. The suggestion is made that no-fault divorce should be abolished for couples with children or that divorce laws should be toughened for parents. .

While it would be great for every child to have two loving parents, it's not realistic to blame no-fault divorce for family breakups. Most states adopted no-fault divorce to take acrimony, pain, legal shenanigans and financial hardship out of marriage dissolutions. By the time a couple reaches divorce court, it's usually too late to patch up an unhappy and unhealthy marriage.

And the numbers of adults and teens in self-help groups for children of alcoholic or abusive parents shows that living in a dysfunctional, if intact, family can leave scars.

Perhaps what we need are fewer professional busybodies telling us what's bad for us and more attention paid to how to make male-female and family relationships work. Divorced and single parents don't need another guilt trip or more hurdles to jump in their already difficult lives.

What's disturbing about this recycled family values' debate is our nation has done so little to promote families. Only recently, for example, did we affirm the policy of allowing parents to take time off work to care for newborn or sick children. Our social policies in most areas involving children are far behind those in other western industrial nations.

And at the state level, only recently has there been a move to reform welfare laws so they don't penalize intact families.

In an article in this magazine in January 1992, Whitehead wrote about how unfriendly our culture is to families and about the need to transform public policy to help parents raise the next generation. That sort of comprehensive approach is what is needed rather than quick fix, busybody, punitive policies.

Elaine S. Knapp

Elaine S. Knapp
*Managing Editor*

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## Letter to the Editor

I agree with Mr. Rosenthal, ethics is high on the public's agenda. However, unless I misunderstood the definition of "Executive Branch" of state government, Mr. Rosenthal is uninformed. He states, "I know of no states where ethics training is offered in the executive branch." Please inform him that several states provide ethics training for executives and managers.

Oklahoma has offered a two-day ethics course for more than five years. Hundreds of state agency executives, managers and supervisors have attended. The course is a requirement in our Certified Public Manager program. We have also offered variations on the two-day ethics course in our week-long Executive Development courses. In addition, I have made presentations on our ethics course to the International City Managers Association national conference and the American Association of Public Administration national conference.

Most states involved in the Certified Public Manager Consortium have some form of ethics training. This includes Alabama, Arizona, Florida, Georgia, Kentucky, Kansas, Mississippi, North Carolina, New Jersey, Utah, plus others. Ethics is a serious training issue in many states.

Please let Mr. Rosenthal know that the National Association of Government Training and Development Directors, an association affiliated with The Council of State Governments, has a directory of training services available in most states.

Larry Fisher, Assistant Administrator
*Human Resource Development, Oklahoma Office of Personnel Management*

# Genetic revolution

*Rapid advances in genetics are affecting state insurance, health and criminal justice policies.*

by R. Steven Brown

A quiet revolution in medicine is taking place. New research on human genetics is resulting in an unprecedented increase in knowledge about the causes of disease.

During the past year or so researchers have found a genetic component for breast cancer, colon cancer, diabetes and some heart diseases, to name a few. The list is expected to grow rapidly over the next few years, and scarcely a month goes by without the discovery of another disease-causing gene, the most recent being the gene for Lou Gehrig's disease, found in March 1993. Usually the discovery of a disease-linked gene is accompanied with statements about increased possibilities for treatment.

Millions will be directly affected by these advances. The new insights are "already radically transforming every clinical discipline and patients' decisions," said Dr. Paul Billings, a geneticist who helped draft a California bill calling for limits on use of genetic data by insurers.

The use of new genetic knowledge to treat disease, called "gene therapy," is anticipated to become as important as immunizations and antibiotics. Gene therapies involve altering or replacing a gene in human cells to correct a genetic problem. At least 10 gene therapy trials are under way, looking at treatments or cures for diseases such as AIDS, cancers, heart

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*R. Steven Brown is the director of the Centers for Health and Environment at The Council of State Governments. He recently completed a book entitled* Advances in Genetic Information: A Guide for State Policy Makers.

disease and cystic fibrosis. Pharmaceutical companies are positioning themselves to produce gene therapy products. Gene therapies promise relief for a wide range of disorders, many of which now have no treatment or cure.

So it may not come as a surprise that such promising advances raise policy challenges for state governments. And not just in the area of health, but also for employment policy, insurance rules and justice issues.

How will advances in genetic information affect the states? Why are genetic discoveries not just a wonderful medical advance to be discussed by doctors and their patients? The answer lies in the ways the new information can be used.

Knowledge about the location of disease-causing genes leads to the possibility of developing a test for the genes. The possibility of testing people for these genes, and then using the information to take preventive action, has not gone unnoticed. Women with a breast cancer gene, for example, might be encouraged to have more frequent mammograms, while those without the gene might need mammograms less often. This could lead to a healthier population at less cost.

There are problems, however, that might come with new knowledge about individual health risks. The information may be used for purposes that do not benefit the individual.

One problem is with insurance coverage. Health insurers that provide individual health policies must establish the applicant's risk before granting coverage. Because genetic risk data is in a person's medical file, which must be released to the insurer, the data might be used to deny coverage. An increased knowledge of individual risk may cause a breakdown of the insurance system, where people who need insurance can't get it, and people with few risks and less need can get it. Even group insurance policies may be affected, if genetic data is used to establish a "pre-existing condition," excluding the applicant from benefits. Several cases of "unfair genetic discrimination" by a few insurers already have been documented. Many people believe it is unfair for a person to lose insurance based on the results of genetic testing for common disorders, when the test was taken for the purpose of helping promote health.

Several states have attempted to head off this problem. Wisconsin passed a 1992 bill prohibiting the use of genetic information in determining eligibility for insurance and continued hearings on the subject this year. Florida passed a bill that requires insurers using "DNA tests" to notify anyone who is denied insurance coverage because of the tests. The federal government also has recognized the potential for problems, creating a task force on insurance and genetics at the National Institutes of Health. Its recommendations are due this month and have already been forwarded to Clinton's health task force.

Because insurance benefits are a major cost to employers, use of genetic information about employees and job applicants is a real concern. The U.S. Office of Technology Assessment found only 3 in 245 surveyed companies used genetic tests to screen workers in 1987, but a larger OTA survey in 1991 found that one in 20 companies was conducting genetic monitoring or screening. State and federal law is unclear about whether workers are protected against genetic screening and monitoring, and what rights they have if denied employment because of a genetic disorder. The situation could become more confused if a potential employee has dependents with a genetic disorder.

The federal Americans with Disabilities Act, for example, protects some people with genetic disorders, but not others. Most state laws are similarly unclear. California's Hereditary Disorders Act of 1990 prohibits "stigmatization" and "discrimination" against "carriers of most deleterious genes," but it is unclear what constitutes a "deleterious gene." Other states, including Florida, Illinois, Louisiana, New Jersey, New York and North Carolina, protect only certain genetic disorders, such as sickle-cell anemia.

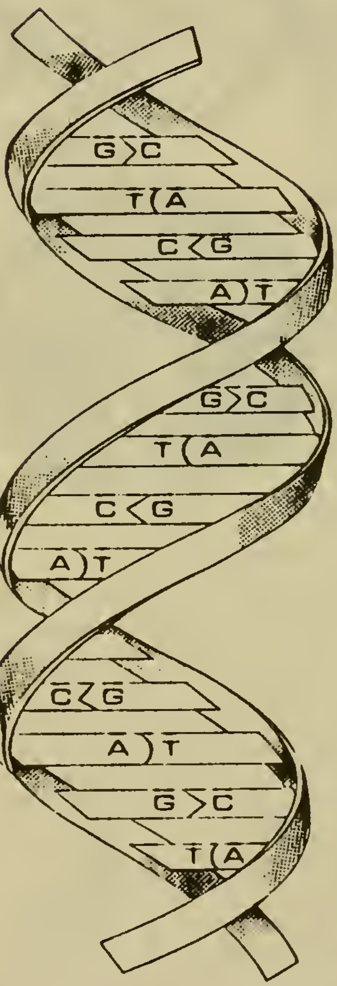
Another area affected by advances in genetic information is criminal justice. The acceptability of "DNA fingerprinting" has expanded rapidly in recent years, despite concerns about the tests' reliability. In DNA fingerprinting a minuscule amount of a suspect's tissues — including hair follicles, semen or blood — can be tested to reveal the person's genes. Since only identical twins have identical genes, it is possible to link a suspect to a crime by using DNA fingerprinting.

A DNA test also can exonerate a person who has been accused or convicted of a crime. DNA testing recently cleared a man convicted of rape in New York.

While the science of DNA fingerprinting is established, there are concerns about errors inherent in laboratory testing of forensic samples. In medical settings, DNA testing is performed under controlled settings, and duplicate samples are easily obtained and preserved. In a forensic setting, only a limited sample may be available, and it may have been altered by environmental conditions. In addition, questions have been raised about techniques and controls used by some private laboratories. So it may come as no surprise that states are mixed on the use of DNA fingerprinting in criminal cases. At least six states have passed legislation to authorize the admissibility of the data; the courts of three other states and territories have ruled the data inadmissible. A national panel called for more proficiency testing, accreditation and independent oversight of laboratories conducting forensic testing.

State public health agencies have been slow to recognize what genetic advances mean for state public health policy. Traditionally, genetics issues have been confined to newborns. All states require newborns to be checked for certain inherited disorders, which, if untreated, will cause serious harm. But recent advances in genetic information are applicable to chronic diseases of public health importance, not just the relatively obscure genetic disorders of a few. The role genetics plays in common adult diseases like cancer and heart disease — the "diseases that vote" — has rarely been incorporated into the planning of state health agencies in other than cursory ways.

Similarly, state universities are failing to produce health professionals capable of explaining the meaning of genetic tests to patients. Genetics is seldom emphasized in medical school curricula — as of 1985, 20 percent of U.S. medical schools had no genetic courses. There are only about 1,000 genetic counselors in the United States, and only 15 principal programs offering graduate degrees in genetic counseling. These programs graduate only about 75 students per year.



Genetic information is sensitive information for several reasons. There is a sense that, because a gene is part of the "blueprint of life," it somehow defines a person. Likewise, genes link us to our kin, so what a gene says about one person may be implied for a close relative. Genes are passed on to children, so there are reproductive implications. There are other implications as well — the Nazis believed that crime was a disease, genetically determined and racially specific. These are some of the reasons that ethicists believe privacy protection should be a priority. Privacy concerns, as well as concerns about forensic DNA testing, are being reviewed by a national Institute of Medicine panel, which will report later this year.

Much of the new information on genetics is occurring because of international support for research. Congress has authorized about $200 million annually to the Human Genome Project (a "genome" is all the information stored on a species' genes). The research is being conducted nationwide, primarily at universities. One reason this research is possible is because of development of automated techniques that allow the painstaking repetitive work needed to determine the content and order of genes. The Human Genome Project is expected to last about 15 years, but it may be much longer before its ramifications are known.

The states have substantial authority over areas affected by genetic advances — health, insurance, employment and criminal justice. To date, states have addressed each issue separately, if at all. States need to consider the policy implications of this rapidly advancing technology before the problems it creates outweigh the benefits. ☐

# Ethics and Agricultural Biotechnology

by Paul B. Thompson
Texas A&M University

The word ethics is often used interchangeably with the word *morality* to indicate goals, norms, and values that are taken to guide human action. In the past decade, several universities have developed research and teaching programs in agricultural ethics. These programs stress the criticism, analysis, and justification of norms as they are applied to food and fiber production, distribution, and consumption. Two methodological approaches are common in agricultural ethics. *Analytic agricultural ethics* describes the concepts, arguments, and norms built into our understanding of agriculture. *Substantive agricultural ethics* is prescriptive, recommending specific action plans, practices, and policies for persons and organizations involved in agricultural issues. The aim of substantive ethics is to present arguments for or against a proposed course of action that apply those concepts, rules, and standards with clarity, rigor, and logical coherence. Analysis of ethical issues strives for objectivity. Substantive researchers assume that the give and take of debate will produce a clearer and more coherent understanding of ethical issues. The program at Texas A&M emphasizes analytic methods.

Biotechnology has been at the cutting edge of agricultural science and technology for a decade. In light of its revolutionary methodologies and its potential for impact upon production, it is not surprising that agricultural biotechnology has been hotly debated. The debate has often been conducted as if facts are in dispute, but while there are disputed facts, resolution of factual questions seldom if ever is successful in resolving debates. In fact, debates over agricultural biotechnology are driven by conflicting interests and values.

Debates over agricultural biotechnology involve ethics in many ways. Three areas of debate have been particularly influence by ethics. One is patents and ownership of genetic materials. A second is responsibility for unwanted and unintended consequences. A third is questions raised by the religious implications of genetic manipulation. Each of these areas of debated are summarized below.

## Patents

Patents and ownership of genetic materials have been debated in connection with Congressional hearings for the Animal Patent Act in 1986 and for several other pieces of legislation that have been contemplated more recently. What sorts of things should be understood as property, and who has a legitimate claim to own them? Since human slavery is thought to be unethical, some have argued that allowing ownership of human genetic materials is also unethical. Also, patent law forbids ownership of "natural laws," or the scientific principles that underlie natural processes. Some argue that genetic information is an example of "nature's bounty," which our property ethics hold should be free and available to all. One can, however, own processes and procedures for producing manufactured goods, and some have argued that biotechnology includes techniques and products quite similar to those currently protected by food processing patents and by the Plant Variety Protection Act.

## Unintended Consequences

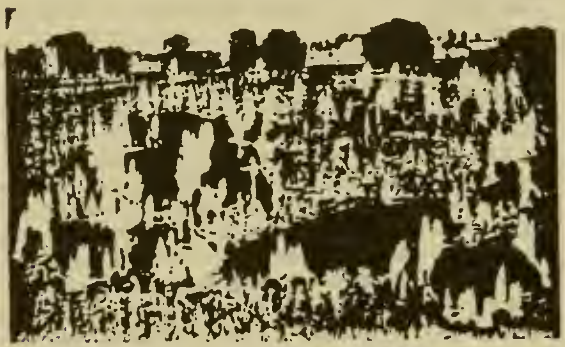
The unintended consequences have stimulated the most acrimonious debate over biotechnology. Beginning in the early 1980s, Jeremy Rifkin's Foundation for Economic Trends has initiated lawsuits and other actions designed to ensure that those undertaking research and development of agricultural biotechnology assume responsibility for all social and environmental consequences. The first round of debate focused on ice-nucleating bacteria that could provide crop protection against freezing temperatures as low as 30° F (-1°C). Rifkin delayed experiments with these bacteria by raising questions about whether scientists had undertaken adequate review of potential environmental consequences.

The second round of debate has focused on recombinant bovine somatotropin (BST), a genetically engineered version of the hormone that can be used to stimulate milk production in dairy cows (See *Science of Food and Agriculture*, January 1989). The unintended consequences that raised concern with BST stressed social impact upon the structure of the U.S. dairy industry. Some analysis predicted that the technology would accelerate a shift from small to large dairies, and from the Northeast to the South and Southwest as principal production regions. Concern over the impact on the health of dairy cows has been raised, largely associated with mastitis problems associated with the increased volume of milk production. Finally, consumer groups have continued to express reluctance to accept milk produced using recombinant BST, despite firm scientific evidence documenting safety and quality.

Each of these questions can be framed in factual terms: what are the effects, intended or not, of biotechnology? Public debate is often conducted in these factual terms, with opponents issuing their own scientific studies to back up their own predictions, while raising questions about others'. The debates continue, however, because Americans have not come to terms with the general problem of responsibility for unwanted impacts of technology. One approach for analyzing the ethics of technical change is to aim at some optimal trade-off between social benefit and social cost. Here, unwanted impacts in the form of environmental impact, social dislocation, and economic or psychological stress would be balanced against benefits associated with increased productivity and lower consumer cost for agricultural products. This approach is difficult to implement because markets do not provide noncontroversial measures of cost and benefit for many of these unwanted consequences. Furthermore, the probability of an unwanted impact from biotechnology may be very low, but when health and environmental risks cannot be eliminated entirely, there is a frequent tendency for low probability risks to assume a high degree of importance in public debates.

In part because of these measurement problems, many have argued that an ethical resolution of the unwanted consequences problem should abandon the attempt to optimize trade offs and should instead concentrate on fair procedures for assuring that all affected have a say in decisions to research, develop, and apply technologies that change their lives. At present, farmers control the decision to adopt, and consumers control the decision to purchase, but choices are constrained by market structures and competitive pressures that arise from new technology. The decisions to develop and market these new technologies are made by businessmen and by research administrators. Although the decisionmakers have indirect public input, there is typically no formal mechanism to inform affected parties or to seek their consent to programs of technological development that will affect them. The issue of consent seems to be especially relevant for food products developed using biotechnologies. Consumers may be quite willing to accept these products if they are offered under conditions of informed consent, but may reject them if they feel that their ability to control their own food choices is in jeopardy.

The difference between these two ways of understanding responsibility is particularly evident for risk issues. Those advocating optimal trade-offs tend to assume that an impact's significance decreases with the likelihood of its occurrence. They often regard public attitudes to risk from agricultural biotechnology as irrational in light of the low probability associated with unwanted human health or environmental consequences, particularly when compared to risks associated with natural causes such as *Salmonella* spp. Those advocating fair procedures, however, place special emphasis upon impacts that are the result of human actions. They do not, for example, expect a naturally occurring microorganism to ask them whether they are willing to be exposed to risks of harm arising from it, even when the probabilities are high. They do, however, expect human beings who introduce a new organism to inform them of risks, and to do so under conditions that allow them a choice.



## Religious Concerns

Conflicts over property rights and unwanted consequences are politically contentious because of the interests that are affected. They become even more complex when religious concerns are introduced into the mix. Biotechnology is religiously significant because for some people, at least, the ability to move genetic material from one animal species to another raises questions about the ethical significance of species boundaries. These questions are of two sorts. First, the creation of genetically modified animals and the recognition that human and animal genomes are very similar have rekindled debates over evolutionary theory. Theologies that propose a difference in kind between human and nonhuman animals are challenged by the new molecular biology. Second, some religious views interpret the existing distribution of species as God's handiwork, and interpret genetic modification of animals as a violation of absolute constraints on human action.

Religiously based concerns often enter debates indirectly, being expressed along with secular ethical concerns about property rights or unwanted consequences. The U.S. tradition of separating church and state may make religiously based arguments seem less legitimate in the public policy context. Whatever one thinks about given religious views, however, it is becoming increasingly important to have an explicit public airing of ethical concerns. As a pluralistic society, Americans should expect dramatic events to elicit a variety of reactions. If we are to avoid lengthy and acrimonious controversy, it is important to fully state the values that influence our views, as well as the facts. Agricultural researchers and producers should pay attention to these ethical debates, and should be sure that their voices are heard.

*Dr. Thompson is director of the Center for Biotechnology Policy and Ethics at Texas A&M University in College Station.*

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# The Brave New World Of Genetic Research

## And the perils of trying to build a better human

*LE MONDE diplomatique*

By Thierry Damerval

The goal of biological research has always been to gain an understanding of the structure of living organisms and the way they function. Work being done on genetic makeup, one of the main components in all organisms, is now zeroing in on many biological mechanisms. Gene therapy is being performed on human beings for the first time, and a project that aims to provide a complete analysis of the human genome is under way in the United States and Europe. This is a prestigious technical feat, and its completion will be the symbolic culmination of the efforts to achieve a thorough understanding of genetics.

The results of research into human genetics represent a great advancement for medicine: Now there is the hope that we can monitor the development of illnesses linked to genetic abnormalities and reduce their consequences. But this also raises a basic question: How should this knowledge be used?

Clinical analyses have already made it possible to link a number of hereditary illnesses to chromosomal aberrations, and genetic analysis makes it possible to detect individuals who have an abnormality well before birth. Insofar as it is possible to make this detection prior to birth, one solution could be abortions, which would eliminate carriers of the aberration. Because genetic material remains unchanged in practically all cells of an organism in the course of its development, analysis of it would enable researchers to study people as they might become. Consequently, medical expenses could be predicted. Even if the decision to abort a pregnancy is the mother's to make, is it acceptable to have financial considerations play a part, even indirectly, in the decision? How should a curable—but very expensive—illness be handled?

Another question concerns research being done on those illnesses—such as muscular dystrophy—that can be detected but cannot now be treated. Should expensive research into cures for such illnesses be pursued if prenatal diagnosis becomes more readily available? The huge fund-raising campaigns no longer seem logical if prenatal diagnosis, combined with abortion, leads to the elimination of the chromosomal abnormality within population groups.

Finally, when serious physical abnormalities dramatically reduce a person's life expectancy, the individual's viability is directly connected to the nature of his lifestyle. What must therefore be added to the concept of predictive medicine is the idea that there is an "ecological niche" that suits each person. This idea, which was developed by one Jacques Ruffié, calls for creating a setting that would permit the full expression of each person's potential, according to his genetic heritage. Technical progress in genetic research has been widely associated with improving the conditions of life: selecting and improving plants and animals for the benefit of humans; battling against illnesses. Traditionally, progress has meant adapting the environment to man's needs. Assigning a person to an ecological niche, however, means adapting human beings to their environment.

Since the structure and composition of an individual's genetic content are unique, genetic "imprints," used for the first time in Great Britain in 1987, are in principle similar to fingerprints. Genetic data can be collected quickly and can help to reveal an individual's traits or potential. Every business selects its staff according to financial and commercial goals; every educational system takes a child's potential into consideration in deciding where to place the child. In both cases, the selection process is often based on methods—such as psychological tests—that aim at judging individuals' capabilities. Genetic techniques provide a rigorousness and a subtle analysis never before obtained.

In the near future, commercial use of genetic-identification tests will certainly be expanded. The threshold has already been crossed with the establishment of a paternity test that can be used by private individuals. The search for biological parents has already been undertaken using this technique in Argentina in the cases of children separated from their families [under the military dictatorship] between 1976 and 1983. There, the situation is such an extreme case that it justifies the use of these methods. Would such applications be acceptable in democracies?

New possibilities are opening up for employment recruit-

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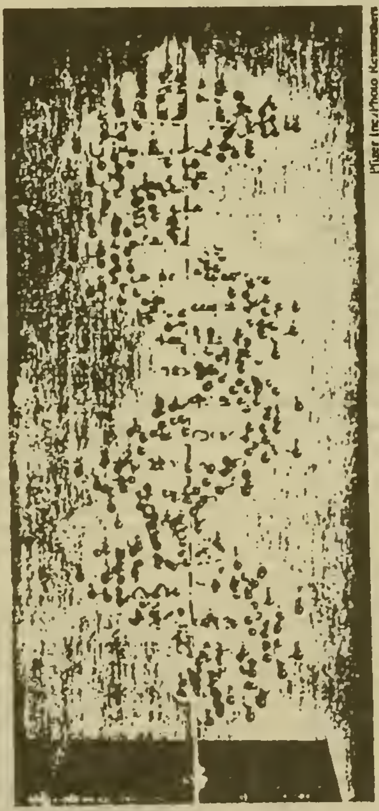
*From the liberal monthly "Le Monde Diplomatique" of Paris.*

ing offices, for insurance companies, and in every area where an in-depth knowledge of an individual is needed. Biology has certainly not remained far removed from these kinds of goals in the past, but now genetics makes the investigation process more potent than at any previous time.

According to a study by the U.S. Office of Technology Assessment in 1983, of the 500 largest American chemical and electronics companies, 23 were using or had used a screening process based on biochemical analyses, and 59 were considering using it in the future. These companies' reactions following these tests, most of which were for detecting hypersensitivity to irritating chemicals, were instructive. Eight companies simply warned their hypersensitive employees that their health could be endangered, five transferred the employees to other posts, and three took safety steps in the offices at risk. One of the companies stopped producing a substance involved, and two others recommended that the hypersensitive workers change their jobs.

Thanks to molecular genetics, tests such as these can now assess an extended array of characteristics. In a 1989 article titled, "Genetic Passport, Critical for Gaining Access to the Job Market," Frans Van den Maagdenberg, a personnel director in the Netherlands, did not hide his enthusiasm: "I am a believer in splitting society into healthy people, on the one hand, and sick people, on the other. This kind of division seems inevitable. The terms 'genetically unproductive' and 'genetically weak' will appear more often." Van den Maagdenberg foresees using "genetic passports" in placing students. Although he recognizes the importance of freedom in teaching, he argues, "It is very practical to know from the start where our chances and our talents lie." The individual could unfortunately be reduced to a collection of genes, though it has been proved that genes are far from being the only factor at work in the makeup of a human being.

Because analyzing genetic material makes predictions possible, the development of specific biological functions can be detected in advance. Huntington's disease and Alzheimer's disease are serious hereditary illnesses that develop only in adults. What will an employer's or an insurance company's attitude be when it is faced with a healthy 30-year-old who it knows will come down with such an illness in a couple of years?



Pfizer Inc./Photo Researchers

**DNA model:** *Predictions are possible.*

The impact of genetic research is undeniable, but the nature of its uses is difficult to foresee. If Van den Maagdenberg's ideas are applied, we are headed toward a society organized according to each person's genetic characteristics: an attempt at eugenics that would be difficult to proscribe, since it is based on economic necessities and not on irrational ideologies. It would be a matter of "democratic eugenics"; its horrible necessity would be felt as time went by. The protection of individual freedom can be insured only by the behavior and moral standards of everyone involved: the researcher, doctor, and clinician—and the user of the information.

Often, knowledge once acquired cannot be separated from its practical application. Is it still possible to do research for the sake of knowledge alone? Since any discovery can easily be put to use, the areas of investigation have sometimes been surprising. Attempts have been made to increase the stamina of high-level athletes and to transmit social attitudes using genetics.

Recommendations for researchers are in no short supply. Numerous articles propose ethical measures that would limit the scope of this kind of research. Genetic research as a savior is presented to us more and more, whether in the fight against hereditary illnesses, toward finding new methods for fighting crime, or for understanding the role genetic factors play in a person's chance for success. The positive aspects of research are always emphasized, but rarely is there any discussion of the complexity of issues it raises.

In view of all this, it is up to each person to think about the possible consequences of putting too much trust in scientific research, as it could be as dangerous for humanity as beneficial. Citizens have to be better informed. In France, high-school biology classes include lessons on "the economic, social, cultural, and ethical problems raised by the accelerated development of contemporary biology" and "the new perspectives now available in medicine and the moral problems." A clear definition of principles is needed, as well as legislation that takes into account all research techniques. The use of genetics is directly connected with the individual's freedom, and existing practices have to be re-examined. The biological revolution taking place at the end of the 20th century will undoubtedly have social consequences as vast as the Industrial Revolution of the past century. ◻

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AUG 21 1993 P. A13

# Result of New Fertilization Method Due in October

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Associated Press

ATLANTA—Hunter Simpson is making history even before he is born.

In October, he will become the first baby in the United States born through a novel fertilization technique, a single sperm injected directly into his mother's egg.

"I've got a Polaroid of my four little embryos I had implanted . . . and one day we'll be able to tell him. 'One of these was you,'" said Claudia Simpson, who had not conceived in five years of in vitro fertilization attempts. Direct sperm injection, however, worked on the first try.

"We'll tell him all about how he was conceived a little differently," added her husband, Pat, who envisions taking Hunter on his weekly television series, The Nashville Network's "Backyard America."

Direct sperm injection is an infertility treatment for men unable to impregnate a woman because of weak or insufficient number of sperm. A single sperm is injected into a human egg under a microscope. Three days later, the resulting embryo is implanted into the mother-to-be's uterus.

"It's almost foolproof," said Michael Tucker of Reproductive Biology Associates in Atlanta, who treated the Simpsons. "All you need is one sperm."

Andrew van Steirteghem of the Free University of Brussels developed the method in Belgium last year. He has reported 100 births, all outside of the United States.

In addition to the Atlanta clinic, the Genetics and IVF Institute in Fairfax, Va., began offering the treatment this year. Claudia Simpson and two other patients of the Atlanta clinic are due to deliver this fall. The Fairfax institute claims the first twins by the process, due in February, and two other pregnancies.

The Virginia institute learned the technique from the Belgians; Tucker developed his own, slightly different method.

Crawford Long Hospital in Atlanta also will begin performing the procedure this fall, when a physician who studied under van Steirteghem arrives.

"It's a major breakthrough," said Joseph Schulman, director of the Virginia clinic, who predicted use of the method will spread quickly. "One to 2 percent of all couples of reproductive age might benefit from this."

> *"One to 2 percent of all couples of reproductive age might benefit from this."*
>
> —Joseph Schulman, director, Genetics and IVF Institute in Fairfax

But other doctors caution that while the direct sperm injection is promising, it is too early to know just how effective the procedure is.

"The technique is so delicate that it can destroy the egg," said Veronica Kavnikar of the University of Massachusetts Medical Center in Worcester.

"And the question will always be, is there some potential for genetic defects?" said Lisa Hasty of Emory University School of Medicine in Atlanta.

Joe Massey, co-founder of Reproductive Biology Associates, wants that possibility studied. Although a battery of tests makes him confident the clinic's upcoming babies are healthy, nobody knows how nature chooses a successful sperm, so doctors do not know what to look for, he said.

"Just because a sperm fertilizes an egg doesn't mean the chromosomes are right," Massey said. "Any increased risk of chromosomal defects has yet to be determined."

But van Steirteghem has not reported any problems. And Schulman said the genes of infertile men are not defective; it is just that the sperm that carry those genes do not move well.

Claudia Simpson, 34, is not worried. Tests indicate her baby is healthy.

The suburban Atlanta couple has a daughter, Lindsey, 6, but could not conceive again because Pat Simpson's sperm were not strong enough to penetrate the jelly-like coating surrounding the egg.

Five tries at in vitro fertilization, the standard treatment in which several thousand sperm are mixed with eggs in a petri dish, failed.

In January, Tucker recommended direct sperm injection. The $9,000 procedure worked.

The Simpsons donated 14 eggs, seven for in vitro fertilization and seven for direct injection. Direct injection fertilized four eggs. One embryo grew.

"So many people now are trying to have kids and can't," Pat Simpson said. "That's our message: Don't just throw your hands up and say you can't have one. Claudia's living proof you can."

CHICAGO TRIBUNE
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Chicago Tribune c 1993
AUG 22 1993 sec. 1 p. 1,7

# Medical dilemma: What price life?

By Ronald Kotulak
TRIBUNE STAFF WRITER

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■ One conjoined twin survives separation surgery. Page 7.

Does a patient have a right to demand all-out, expensive medical care, even if the odds are overwhelming that it will do no good?

Does a physician have a responsibility to tell a patient when further care is futile and not provide it?

The case of 7-week-old Amy and Angela Lakeberg, conjoined twins who shared a deformed heart and liver tissue, goes to the core of what many experts believe is a major cause of out-of-control health care costs in the U.S.—spending too much money where it does little good, such as end-of-life heroics, while not spending enough on things that would do a lot of good, such as preventive medicine.

Physicians at Loyola University Medical Center in Maywood recommended against surgery to separate Amy and Angela. No twins so joined had previously survived separation attempts.

Surgeons at Children's Hospital of Philadelphia said they would give it a try even though they knew one of the twins would die on the operating table and the other had less than a 1 percent chance of surviving. The doctors saved Angela; as of Friday night, she was in critical condition.

The question remains: Who's right? Is it more ethical to use the money to help other children with better odds? Or is there a higher moral value in saying no cost is too high in trying to save a baby's life? And how should these decisions to spend public money be made?

There are no easy answers, especially in a country where the

SEE ETHICS, PAGE

# Ethics

Continued from Page 1

slightest chance of saving a life attracts great interest.

"We shouldn't underestimate the moral force in the attempt to rescue," said Bruce Jennings, executive director of the Hastings Center, a medical-ethical think tank in Briarcliff Manor, N.Y. "Even when the chances are very slim, none of us would want to completely eliminate that feeling from our society. In many cases, it's very humanizing and something to be proud of."

But in a country with skyrocketing health care costs and millions of people unprotected by any kind of health insurance, the widespread practice of spending a lot of money on medical gambles that don't pay off will have to be revised, he said.

Modern technology has created a number of ethical quandaries in medicine. For example, the plights of Karen Quinlan and Nancy Cruzan had to be played out before the nation so people could begin to accept new concepts of life and death.

From their sad, sometimes freakish stories came such things as a new definition of death that depends on a lack of brain function rather than a cessation of breathing and heartbeat, the standard of death that had stood throughout history. The new definition became necessary because artificial life support systems could keep bodies alive indefinitely even though brain activity had stopped.

Wrenching changes also came in the most fundamental concepts of the way humans deal with one another. Doctors and ethicists drew up new guidelines for withdrawing life support and feeding tubes from people who are brain dead or in persistent vegetative states when it became obvious such measures were creating a population of zombies.

For the Lakeberg twins, modern technology played a dual role. Ultrasound enabled doctors last December to diagnose the conjoined babies early in pregnancy and that they likely shared major organs. They recommended an abortion, which the twins' parents turned down.

After the twins were born, doctors conducted extensive tests and then advised the parents against surgery.

"I told the parents, 'Let's take them off the ventilator. Let's hold them and keep them warm. Let's put them in God's hands,'" said Dr. Jonathan Muraskas, the Loyola neonatologist who agonized over his recommendation, knowing full well the twins probably would die in a couple of days if the parents took his advice.

They didn't. They chose to have surgery despite the fact it meant that one of the twins would die on the operating table and the other had less than a 1 percent chance of surviving.

"It's like people win the lottery every week," the father, Kenneth Lakeberg, told reporters. "Why can't we win on life? Why can't we gain a life here and defy the odds?"

Although Loyola said "no" to the surgery, surgeons at Children's Hospital of Philadelphia said they would give it a try, despite the odds.

After the surgery, chief surgeon James O'Neill was asked about the ethics of sacrificing one baby to save another.

"There has been a unanimous consensus that if it is possible to save one life, then it is worth doing this," he said.

Even if Angela survives beyond the first critical weeks, she will have to be kept in a high-tech cocoon for a long time, expensive care that could end up costing $1 million or more.

So far, the cost of caring for the twins at Loyola is about $300,000 and the Indiana Medicaid program has agreed to pay about $1,000 a day for their care at both hospitals. The Lakebergs have no medical insurance.

There are two important issues here.

One is that a woman can't be forced to have an abortion against her will, Jennings said. The second is that the parents are being placed in a position to command social resources that arguably they don't have any right to command, he said.

"It's not fair for them to be able to demand $1 million worth of care for their babies even though we know it's not going to work, while millions of parents can't afford to have their children vaccinated," Jennings said.

"But you can't fault them for trying," he said. "I fault the system. It's not irrational or immoral for people to ask for a chance to pull out all the stops on medical care despite the fact that there's no hope. The problem is that we're saying 'yes' to all of them who are asking and it's making us go broke."

The pressure to provide extraordinary levels of care gains momentum when a case attracts media attention, especially if the patient is a baby.

Other nations have dealt with the problem by rationing health care. Last week in England, Harry Elphick died of a heart attack after being denied coronary bypass surgery.

British doctors denied the surgery on the grounds that Elphick was still smoking and that smokers had poorer outcomes from this type of surgery.

"Patients who continue to smoke after surgery don't have any survival benefits," said Dr. Colin Gray of Wythenshawe Hospital in Manchester who made the decision to withhold surgery. "They don't live any longer than if they haven't had an operation. These are the hard facts."

In Oregon, the first state to attempt to come to grips with costly medical care that has little or no benefit, surgery to separate conjoined twins is not on the list of procedures that the state's Medicaid program will pay for.

"Our primary purpose was to provide universal access to health care in Oregon," said Gwean Baldwin of the governor's office. "How we went about doing that was to acknowledge the fact that we can't pay for everything for everyone.

"For $300,000, we could completely immunize 3,000 children."

The Oregon Health Plan is set to start in February. From a list of 668 medical treatments, doctors and other experts selected 568 that the public assistance program would pay for because they were considered to be beneficial.

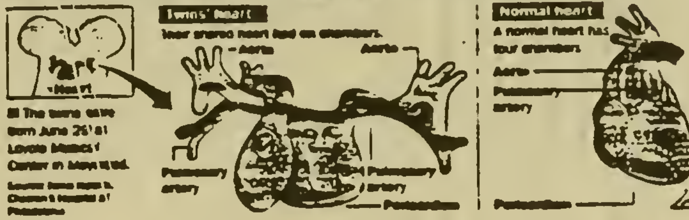
Procedures that the plan will not pay for, either because the conditions get better on their own or the treatments offer marginal improvement, include care for the common cold, therapy for chronic back disorders, cancer surgery in terminal cases and treatment for minor head injuries and infectious mononucleosis.

The money saved by cutting out these treatments will be used to help expand Medicaid coverage to 120,000 people, mostly the working poor, who are now without medical insurance but who otherwise would not qualify for Medicaid, Baldwin said.

"Right now we don't have a very orderly way of setting priorities on what is medically beneficial and what we'll pay for," Jennings said. "Maybe the Oregon plan will lead the way."

## Surgery on conjoined twins

Conjoined twin Angela Lakeberg was in critical condition Friday after surgery to separate her from her twin, Amy. About two-thirds of their shared heart had to be reconstructed to enable Angela to survive. The shared heart lacked enough tissue to enable Amy to survive, doctors said.



■ The twins were born June 29 at Loyola Medical Center in Maywood.

Sources: [illegible] Children's Hospital of Philadelphia

Chicago Tribune

# A time of hope and tears as twins are separated

By Karen Brandon
Tribune Staff Writer

PHILADELPHIA—In the gray haze of Friday's pre-dawn, Reitha and Kenneth Lakeberg bade their baby girls farewell, knowing one would be sacrificed to offer the other the slimmest chance at life.

After a sleepless night, the Wheatfield, Ind., couple stood praying in a third-floor room in Children's Hospital of Philadelphia—their final destination in an odyssey against all odds and advice to save one of the twins, born seven weeks ago joined from collarbone to belly.

Only the crying of the adults was audible. The babies, Angela and Amy Lakeberg, always had cried in a silence imposed by the respirators that kept them alive.

In those final moments with the girls, their parents and an aunt looked for any encouraging sign in a mission that seemed so fraught with futility, pain and expense that many in the medical field questioned it.

"We was standing praying, and Angela put her thumb up," said Georgia Welsh, their aunt.

Seeing it, their mother, Reitha "Joy" Lakeberg, replied: "'That's right, Angel,'" Welsh said. "'Thumbs up, honey. Thumbs up.'"

Only after the girls were wheeled away at 7 a.m. did Georgia Welsh utter the question she said the parents could not bring themselves to ask.

Dr. James O'Neill Jr., one of the world's most experienced surgeons in the separation of conjoined twins, answered: They would try to save Angela.

Some 5½ hours later, doctors said the complex operation had been completed and that Angela had survived.

She was listed in critical condition Friday night in the hospital's intensive care unit, still attached to a ventilator. Doctors said they would know more about her prognosis in the next two or three days.

It was only the latest of long shots the family had conquered. They chose to carry the twins to term though doctors advised an abortion. The June 29 birth of the babies was in itself unlikely. Most conjoined twins are stillborn.

A rather matter-of-fact briefing in which doctors capsulized the day's events belied the drama of what had taken place.

Doctors refused giving any odds on Angela's recovery, saying each situation is unique.

"It is obviously too early to predict what the outcome will be," O'Neill said.

He reminded the throng gathered before him that to date no one with a conjoined heart has become a long-term survivor of an operation to separate twins.

The Lakebergs Friday said in a written statement provided by the hospital: "It's a miracle. We would like to thank all those who were involved."

O'Neill, who headed an 18-member team through the intricacies of separating the twins' bodies, gave a different assessment.

"I don't honestly think that anything we do in medicine is a miracle," he said. "I think it is the product of human effort and human beings."

His hands clasped behind his back, O'Neill recounted what had happened in the operating room. The first work was to separate each of the babies' internal organs, he said.

Dr. John Templeton, who had led the first part of the surgery, joined O'Neill in telling how the team worked to divide the girls' shared liver, giving the largest section to Angela. Her anatomy gave her the best chance of survival, O'Neill said.

Then the team began working on the next critical step—the repair of the heart. The twins shared a heart with six chambers, two more than normal. O'Neill said the repair work was difficult because it involved getting into "the angles, corners, nooks and crannies of the heart."

Angela does not have a normal heart even now, he said. But so far, he said, the heart is beating regularly and pumping blood throughout the body.

Surgeons then completed the separation and closed Angela's chest, he said. O'Neill said Amy died during the procedures involving the heart repair.

MICHAEL S. BROWN • FRANCIS S. COLLINS • JOSEPH L. GOLDSTEIN
JAMES D. WATSON • NANCY SABIN WEXLER

# Roundtable: The Human Genome Project

> *"What we're witnessing is evolution in action. And evolution often isn't kind to the individual."*
> *—James D. Watson*

*The mapping of the human genome, described as the most ambitious undertaking in the history of biology, has the power to change our understanding of life at its most basic level. Scientists working on the Human Genome Project, an international effort to locate and catalogue every gene, are unlocking the mechanisms of inherited disease. But the ability to identify people who have or carry genetic diseases inevitably will come before treatments are discovered. As a result, each success in the gene-mapping project will create new ethical and social policy dilemmas.*

*This discussion is abridged and edited from a forum held May 6 to celebrate the University of Texas Southwestern Medical Center's 50th anniversary. The participants were:*

*Michael S. Brown, regental professor at UT-Southwestern, who won a Nobel Prize in 1985 for his work on cholesterol metabolism. That research was based on studies of a hereditary disease, familial hypercholesterolemia, that can result in heart attacks before age 20. Brown, who served as moderator of the discussion, posed questions from the audience (noted in italics).*

*Francis S. Collins, director of the National Center for Human Genome Research (NCHGR) at the National Institutes of Health (NIH), has served on the executive council of the Human Genome Organization and participated in the cloning of genes for cystic fibrosis, neurofibromatosis, and Huntington's disease. He is currently pursuing a gene for familial breast cancer.*

*Joseph L. Goldstein is chairman of molecular genetics at UT-Southwestern and cowinner with Brown of the 1985 Nobel Prize.*

*James D. Watson, director of the Cold Spring Harbor Laboratory, was founding director of NCHGR. Watson was a cowinner of the 1962 Nobel Prize for discovering the double-helix structure of DNA.*

*Nancy Sabin Wexler, professor of clinical neuropsychology at the College of Physicians and Surgeons of Columbia University and president of the Hereditary Disease Foundation, is chair of the NCHGR/NIH/DOE Joint Ethical, Legal, and Social Issues Working Group. Huntington's disease runs in her family, and she has devoted her career to understanding the genetics of this neurological disorder through extensive field work in Venezuela. With Collins, she was part of a team that traced the Huntington's gene to its location on the "map."*

**Brown:** *Most legislators know little about genetics, and policy is lagging behind progress in science and technology. Can we expect Congress to make wise decisions about how society should manage individual genomic data?*

**Collins:** When you look at how decisions get made about difficult technical issues in the Congress, it's usually the health aides that are out there trying to understand the issue and then passing the information along to the member of Congress with a strong recommendation about how they should vote. Now, maybe that's not the way it ought to be (because I don't think too many health aides were elected), but in fact that is the way things are. I do believe that the genome project has a mandate of major proportions to take on the challenge of public education, and particularly education of legislators, about genetics. That will certainly be a big emphasis of mine over the next few years.

**Brown:** Social policies that are designed for one group may actually harm another group of people who are genetically susceptible to whatever manipulation occurs.

**Brown:** *Are there any anticipated regulatory guidelines under which consideration for availability of genetic testing, quality control, and test-related counseling will be regulated given the serious nature of abnormal results?*

**Wexler:** There isn't anything specifically as a policy on the books. The FDA is supposed to be in charge of performing proficiency testing. But the FDA is so overwhelmed and overburdened that it is extremely unlikely the FDA is going to go into all the labs and make sure that they are doing it right. I think that one of the problems is that it is technically possible to do multiplex testing, which looks for a number of genetic abnormalities at the same time. Many people are concerned that because this is technically possible and economically more efficient, it will be implemented even though it can be extremely deleterious psychologically. As a patient, how are you going to give informed consent for each one of those tests? Do you want to know if you are going to die of ALS (amyotrophic lateral sclerosis)? Do you want to know if you are at risk for breast cancer? Just because you can do those tests together doesn't mean that they should be stacked. A new information-storage technology called the Smartcard poses another problem. In an experiment in Houston, patient medical records are being stored on wallet-size cards that the individual can carry. Doctors and hospitals have computers that can read these cards and also update them. This can be useful to someone who is injured in an accident and rushed to a hospital. But this card can contain private medical and, soon, genetic information. It's really open access for almost anybody who wants to take that Smartcard and plug it into a computer. A number of different organizations—the Institute of Medicine, the National Institutes of Health, the Department of Energy, Congress—are very concerned about it. But one of their reactions, unfortunately, is to say, "Boy, what a can of worms. Why don't we take the money away from the research until we get the ethical problems worked out?" You know, that is just compounding the problem. Because it's when you're in this hiatus, when all you can do is diagnose and you can't treat, that all these problems are going to be exacerbated. If we actually had a treatment and a cure, we could get out the other end. But slowing down the research is not the answer.

There will be insurance reform. I think that that's unquestionable. When Clinton was elected, our insurance task force changed complexion overnight. And suddenly, certain recommendations such as doing away with medical underwriting, that had gotten nowhere, were being agreed with even by the insurance industry. So I think that there will be a lot of change.

**Watson:** When science makes possible the cloning of a gene for a serious disease, but can't immediately come up with a cure, abortion provides a means to remove the gene from a family, if the prospective parents are willing to be tested. This is necessarily complicated, because for example, parents would have to know themselves whether they're going to get Alzheimer's in order to make the decision that their children would not carry on that disease. Likewise with the breast cancer gene. There will be some women who, knowing they're at risk for breast cancer, would prefer their daughters not to go through that same struggle.

Thinking this way, however, evokes moral considerations that many people find very repugnant. It smells of what in the past has been called eugenics, an active attempt to improve the germ plasm. But as

Nancy Wexler knows very well, being born into a family with one of these diseases is no treat. Obviously, we're going to try to cure such diseases through conventional pharmaceutical approaches. We will also try to devise gene therapy approaches. But as with many other medical problems, I suspect that prevention (that is, using abortion) will prove in the long term more cost-effective, if not more humane, than most foreseeable curative treatments.

> *"In this hiatus, when all you can do is diagnose and you can't treat, . . . problems are going to be exacerbated."*
>
> *—Nancy Sabin Wexler*

**Collins:** I think this is an area where one gets quickly into deep waters, but we must never make the mistake of presenting the genome project as having a particular point of view about prevention through prenatal diagnosis. As a physician and genetic counselor, I believe the decision about what to do with prenatal genetic information belongs to only one couple. They are the people involved in that decision and the ones who will live with its consequences. As we discover more genes, we will increasingly put people into difficult positions where they have information that potentially could be used prenatally. Increasingly, we'll be talking about conditions that are not lethal diseases in the first year of life, but are compatible with long and meaningful survival. Then the issues will be brought into even sharper relief. What we must not do is to impose a point of view upon the public that the "right" thing to do with such information is this or that. This has to remain an individual decision, and counseling has to be done in a way that completely preserves that.

**Watson:** I totally agree that it's got to be the individual choice of the people involved. Education is very important. Now you could make a convincing argument that all prospective mothers should be screened for the Fragile X condition (one of the most common inherited forms of mental retardation).

**Collins:** Voluntarily, of course.

**Watson:** Oh, voluntarily. What I mean is, all women should have the choice. In particular, we should work toward getting the test not only available but cheap. Then, if you do not get yourself screened and if your child is born mentally affected, there will be the ethical problem of the guilt feelings arising for not using the information that is available that would have prevented the birth of a tragically impaired child.

**Brown:** We already do that now in screening for Down Syndrome in older women, so there certainly is a precedent for doing that kind of thing.

**Collins:** One other point is that when you're looking at inherited abnormalities—be it cystic fibrosis carrier screening or screening mothers who may pass on the Fragile X gene—if we're really interested in preserving peoples' options, we have to start rethinking the setting in which this is being done. We have in this country this assumption that genetic testing is done when you go for your first prenatal visit to the obstetrician. That does not preserve all the options that a couple might want to have. We ought to try to protect people's options and do those screens before the onset of a pregnancy.

**Wexler:** I think one of the difficult things and one of the challenges for the counseling is how to really present a balanced view. Everybody gives lip service to informed consent and counseling, and everybody supposedly does it voluntarily. But if you ask a lot of women how they found out about amniocentesis, particularly women who don't speak English, they'll say that some doctor said, "Go down the hall. Make an appointment." And that's what passes for informed consent. So I think we need to be extremely careful. There are people with genetic disabilities who feel threatened by the human genome project, who believe that it's saying people with genetic disorders such as cystic fibrosis or spina bifida shouldn't exist. And the fact that we will have tests that will allow people to abort for these conditions is tantamount to saying that we want people with these conditions out of our society.

On the other hand, there are many couples who want to avoid having a child who suffers from these conditions. We've had meetings with people who feel strongly on both sides of the issue trying to thrash out how you can present options so that people feel that if they want to have a child who has a genetic condition they're perfectly free to do that, and if they want to avail themselves of abortion, they're perfectly free to do that. We also must learn how not to demean or diminish anybody who continues to have that condition.

I think these are tremendous challenges. Since most of the testing is probably going to go on in the doctors' offices, who is going to give this information? If you think about how much time a doctor spends with a patient, you have to ask: Who sits down and talks to you about this? There are only 1,000 trained genetic counselors—M.A.- or Ph.D.-level—in this country. So who's going to do the counseling?

**Brown:** *Would the panel please comment on NIH's recent decision to halt funding for clinical genetics training programs. The practicing physicians in the audience need to express their concern that the specialists they will depend upon to guide them in caring for patients in this new era may become an endangered species. Is that really true? Have you heard that the NIH is halting funding for clinical genetics training programs?*

**Watson:** It doesn't surprise me because I think we're all aware genetics is very controversial. It will always be so. Genetic differences exist and we're going to have to learn to live with them and to try to improve the lives of those who've been treated very badly by mistakes in DNA replication. But it will always be scary to think that you're different in a way that puts you at a disadvantage. So many people want to deny the fact that such differences exist. Most extreme was the situation in Stalin's Russia, where conventional genetics was banished under the edict that all human differences were due to the environment as opposed to genes.

On the other hand, you must realize the positive effects. If you can tell a woman with a family history of breast cancer that she's not at risk, that is an enormous benefit. It is also a benefit to a woman who learns that she might be at risk and then does something about it. So there's an inevitability to further accumulation of genetic knowledge. We have to get it. But it's going to be very complicated dealing with it. I suspect we underestimate the effect genetics is going to have on medicine and on human life. What we're witnessing is evolution in action. And evolution often isn't kind to the individual. That's why it's so important to increase our programs on ethics. Every time genetic knowledge is misused—when people are tested without their knowledge or given information they don't really want and can't live with—the issue is going to appear in front of Congress.

A year ago before Congress, I indicated that the human genome initiative's ethics program, which started out as 3 percent of our budget and had grown to 5 percent, should soon go to 10 percent. When I said that, I sensed several congressmen began to have second thoughts about the desirability of the human genome program because of the problems it would create. But many people who have children or family members with genetic diseases have awful problems now. So it's not as if we are creating a whole new set of problems. They exist. It's how we handle these problems.

**Goldstein:** One solution might be that each foundation for each disease could develop ethical guidelines. Each disease has its own set of unique ethical problems—the breast cancer problems are different from the hypercholesterolemia problems or the Tay-Sachs problems.

**Brown:** *How would the recent effort to sequence all expressed genes, which should be achievable in two years, influence the Human Genome Project? That is, many people have proposed instead of sequencing all the chromosomes, just sequence the messenger RNAs and that will tell you all of the expressed genes and then you don't have to sequence all the DNA in between the genes.*

**Collins:** As the questioner obviously knows, 85 to 95 percent of the DNA seems to be junk. You could argue that the most interesting part is the stuff that ends up in RNA. And you can then recopy that RNA back to DNA and it's called cDNA. So why don't we just sequence all of those cDNAs that we know are coding regions and ignore all the introns and junk in between genes? There is an enormous amount of useful information being derived right now by people who are sequencing cDNAs, almost all of which is going on in the private sector. The private sector has figured out that, base-pair-for-base-pair, this is the kind of information that may have the most usefulness biologically. However, the private sector is not doing this out of the goodness of its heart. Nor should one expect that it would. The private sector is there to make money, and its hope is that by sequencing these cDNAs it will uncover some that might be turned into a product some day. So the real question is to what extent will those sequences be made publicly available? If they are made available, well, great. We're getting all this Information and we're not having to spend the U.S. taxpayers' money. What is crucial and isn't happening for the most part, however, is to put these cDNAs on the map. Having a sequence is great, but if you don't know on what chromosome it is, then it's useless to somebody who's hunting a gene for a disease and knows that it maps somewhere on chromosome 8. That part of the problem has really not been solved. I think over the next year or two the genome project in the United States is going to pay a lot of attention to this issue of getting the cDNAs on the map by some method or another.

> *"The decision about what to do with genetic information belongs to only one couple."*
> *—Francis S. Collins*

**Watson:** I think we knew from the very start that the cDNA information would be very useful. Whether it was the right decision or not, we didn't emphasize it in the beginning, believing that the real first thing to do was to get the physical maps on which to place the cDNAs. But in any case, I don't believe the cDNA project will be done two years from now. (Many rarely expressed genes won't be discovered and of those described, only partial sequences will be known.—J.W. note.)

**Brown:** *How would you rate the level of international cooperation now in information sharing and technology sharing?*

**Watson:** I think it's very good with minor exceptions. After the flap about cDNA patenting, the English decided not to put their cDNA sequences into GenBank. The bureaucrat involved really didn't know what he was doing. Incompetent government officials are not limited to the United States. Certainly, the cooperation now between the big French lab (Genethon) and the United States is extremely good. However, when you get close to an interesting scientific discovery, you don't get much collaboration in many cases, even within a country. As long as the breast cancer gene is 20 megabases away, people are quite willing to talk. If you say it's within a half a megabase, then . . . . But I don't think we should get upset with such people. If they're close, they deserve some time to follow up what they're doing.

**Brown:** *I think one thing that shouldn't be underestimated is the need in this whole field for astute clinicians who can find, collect and observe families. Do you people see that as a rate-limiting feature right now?*

**Collins:** That's one of my favorite soapboxes. I am concerned that, while we're developing all this wonderful infrastructure of genetic and physical maps, we're just sort of counting on having the families to be analyzed when we're ready for them. We may find ourselves a few years from now with a wonderful set of tools but an incomplete set of collected families with which to understand disease. The genome project itself can't take responsibility for all that, but we'd certainly like to nurture that activity in a more effective way than we have so far.

**Goldstein:** Well, in fact, it's going to be these large families with diseases such as alcoholism, manic depression, and schizophrenia that are going to be crucial. A gene has already been claimed to have been isolated for each of these three diseases, but the original data have not panned out. The real problem was that the families weren't large enough, and multiple families were pooled for analysis. I hope physicians who see large families with these neurological or psychiatric diseases will bring them to the attention of researchers.

**Wexler:** You don't need to find a family with 13,000 members, as I did with Huntington's disease, but it certainly helps. I have just been struck over and over again by how many times having this huge family has really made the difference in localizing the gene. When we had found one early marker in the Venezuelan family in 1983 and then tested it against the largest North American family, it wasn't significant. If we didn't have the large family to go back to, we would have just kept on churning out other markers because we thought from the computer analysis that the North American family was big enough to detect linkage. In almost every instance in which a gene has been found there's been some people, or sometimes only one person, that's critical—that has a recombination event or translocation or some way of demarcating the region from that huge territory on the chromosome. These people are absolutely essential. It's also crucial to make the right diagnosis. I've seen Huntington's and other diseases where misdiagnoses have seriously misled people for long periods of time. There has to be tremendous cooperation and collaboration between clinicians and the molecular biologists. Families are rate-limiting steps for Alzheimer's disease, for example. In spite of all the people that have Alzheimer's disease, the molecular biologists cannot get enough DNAs from large families into the lab. So there has to be a much more intensive communication. There again, I think that the lay groups—the voluntary health organizations—are tremendously important because they can be a way of bringing families in. In fact, they are working on ways to have better informed consent so that families can participate in research. Can I add one thing to what Dr. Goldstein said about the voluntaries developing protocols for counseling. I think that's a terrific idea. But the problem is that the protocols aren't used. There isn't any enforcement. With Huntington's disease we developed a terrific protocol that included three to six hours of counseling prior to testing and all kinds of assessments. But people just say, well, the insurance doesn't cover it, or it's too long and people don't need it, and they toss it out.

**Brown:** It's not just collecting families with diagnoses. It's the really astute clinician picking out from a number of people who have what looks like the same disease one group that seems to be a little bit different and realizing that in that particular group the gene seems to be inherited in some special way. I can't tell you how absolutely crucially important astute clinicians are to this whole thing, with due respect to Dr. Watson.

**Watson:** No, I think you're right. It's just that we need clinicians who think in terms of genetics. And right now, because genetics was not seriously taught in most medical schools, most clinicians do not know genetics.

**Collins:** It's very difficult, I think, for physicians to carve out time to learn about something that is not an immediate part of their practice.The result of that is that we're going to have this sudden crash program on the day that the first presymptomatic DNA test is released, which is probably two or three years from now. And then we're really going to have to move fast.

**Brown:** There's no question the recently announced discoveries of breast cancer and colon cancer genes are going to create a landslide.

**Watson:** It will change the whole nature of the game.

The CHAIRMAN. Senator Hatfield, we want to thank you for raising these issues. As we were hearing from the OTA, a number of countries around the world have established commissions to try and deal with some of these issues, and you are familiar with the efforts that have been made in Congress. We developed the National Commission on the Protection of Human Subjects in 1974 which functioned very well. Just prior to the time that you came in, I mentioned our committee hearings on the Ralph girls, the sterilization, the syphilitic study, the CIA tragedy in terms of their agents that were taking hallucinogenic drugs, and the Depoprovera utilization in Tennessee.

The National Commission was made up of first-rate individuals whose only authority was just to publish their recommendations in the Federal Register. Their guidelines were accepted by all of the various agencies where they were looking at informed consent and other matters.

You are very familiar with the past Federal bioethics bodies—especially the last congressional body which unfortunately was caught up in this very difficult issue on abortion and was disbanded before it completed its work. And so as you have pointed out, we are in limbo, and there are enormously significant and important issues and questions that need to be addressed.

So I want you to know we welcome the opportunity to work with you to try to address these questions: What is the best way of establishing a commission? How should the members be named? Whether it ought to be done at the executive or congressional level? We are enormously interested in working closely with you. I think it is entirely appropriate that this be a matter for action in the Congress, and we are going to hear later in the afternoon from some individuals who have spent a good deal of time thinking about this. We will look forward to working with you on this measure.

Senator Hatfield. Thank you.

The CHAIRMAN. I am very hopeful that we can try and take some action in this field. It is enormously important for the reasons that you have outlined and for some of the other reasons as well. And so we are delighted to have you here, and we will look forward to working closely with you.

Senator Hatfield. Thank you. And, Mr. Chairman, may I just add one word? You are so accurate in pointing out these past efforts, and I note that they were well intentioned and overcome probably by mostly the abortion issue. But I think there are events that have occurred since that time that even make it a sharper focus on the need for action.

I mentioned the Hemlock Society—that happens to be founded in my State—making rather significant gains and adherence at least to their general principles. I think the fact that Dr. Kevorkian's case has become certainly subsequent to those previous efforts a focus. I think the NIH's request for 2,000 patents, all of these really have raised the level of understanding, plus the fact that I hope on the abortion question that even though you and I hold different viewpoints on that question, that the rhetoric may be reduced in level and intensity enough to understand that we have much in common if we worked for those needs to make abortion a moot issue, I think in terms of infertility and birth control studies.

As you know, we have introduced legislation to create such centers because of the liability factor only one pharmaceutical house is studying contraception today, and get perfected contraception. I think with better education we can understand the biological aspects of those decisions before the fact rather than after the fact.

I think there are so many ways that we can even take the abortion issue and lower the emotional level and work for that mutual concern about making it a moot issue. But there are these other things that are happening that, again, I hope we are not overwhelmed by those events that we are not acting as we were by the abortion issue, unfortunately, which overwhelmed us in the efforts that we had previously attempted to make.

So thank you again for the opportunity.

The CHAIRMAN. I just remembered that we included in the NIH reauthorizations both infertility and contraceptive, support for centers in those areas. I could not agree with you more. I will not hold you much longer, but one of the very special centers that means a lot to the family is the Kennedy Institute of Ethics at Georgetown, which was really initiated by my sister, Eunice, and her husband Sarge. It has done a great deal to develop the biomedical ethics field. It has also worked closely with the Harvard Divinity School and Yeshiva.

They had this incredible story about this individual child who had a medical difficulty and was born retarded, and the question was whether the parents were going to authorize an operation, which was 96 percent effective. But the parents did not authorize because the child was born retarded. It was the whole range of ethical issues that were involved, both for the parents, the hospital administrator, if they were to take on the responsibility to give the authority to perform it, and then the 4 percent, what would happen to the liability? The nurses who saw the child in the nursery and saw the child eventually die because of the inability to try to provide nourishment, and taking each element in terms of both the medical profession and the anxiety and turmoil for that whole medical center, that situation. So it is something that is very, very real and that is reflected in a variety of different ways and is something that involves people in a very real and important way. And so this kind of commission can be of enormous value to our fellow citizens.

We look forward to working with you.

Senator Hatfield. Thank you.

The CHAIRMAN. We will come back to Robyn Nishimi, and we thank you very much.

Ms. NISHIMI. As I was saying, of the four entities that OTA reviewed, we found general consensus that the first three—the National Commission, the President's Commission, and the EAB—were largely successful. The fourth effort, the Biomedical Ethics Advisory Committee, was deemed a failure.

OTA found that several themes that persist across the success stories were notably absent with BEAC. As might be expected, adequate staffing and funding improved the chance of success. Successful commissions were relatively free of political interference, had flexibility in addressing issues, were open in their process and dissemination of findings, and were comprised of a diverse group of individuals who were generally free of ideology and who had wide-ranging expertise.

Based on our review, OTA identified three basic types of organizational models that should be considered for a new initiative. First would be a standing or a continuous body; the second, term-limited; and the third, an ad hoc approach.

We also identified two general classes of issues for which bioethical analyses have been applied: specific classes of, or protocols in, biomedical or behavioral research involving human subjects; and, second, broad-based issues related to medical practices, health care, or the social implications of research. In fact, the scope and issues Congress believes a commission must address could determine the most appropriate structure.

For example, OTA concurs with the National Commission's recommendation that a standing body is appropriate to consider the ethical implications of certain protocols or classes of federally funded research. In fact, the Ethics Advisory Board, established by departmental regulations, was intended as a standing body for such purposes after the National Commission concluded its work in 1978. But in 1980, the Department of Health and Human Services disbanded the Ethics Advisory Board at the direction of the Office of Science and Technology policy. As OTA first pointed out in 1988, by taking this action the Department violated and continues to be in violation of its own regulations that govern the protection of human subjects involved in biomedical and behavioral research.

A term-limited body could address either type of issue, but might be most well suited to the types of reports produced by the President's Commission; that is, broad-based topics arising from Federal activities or interest in medicine, health care, or research.

Finally, ad hoc bodies can be convened for either narrow or broad-based topics, but OTA found consensus that ad hoc initiatives are the least desirable mechanism to address bioethical dilemmas.

Finally, regardless of the type of model that might be chosen, OTA identified six factors that will be important to the success of any new effort: the budget; the mandate and agenda; the appointment process; the bureaucratic location; the target audiences; and reporting and response requirements.

In conclusion, Mr. Chairman, past bioethics efforts have been varied, innovative, and largely successful, but not enduring. Yet in only 2 decades, U.S. bioethics commissions have had lasting and measurable impacts.

As the 21st century approaches, Congress and the executive branch face policy dilemmas that require an understanding of bioethical considerations, as well as legal or economic dimensions.

The issue facing Congress today is how best to incorporate bioethical analyses into policy decisionmaking. It is a task made especially difficult as fiscal realities mean fewer Federal advisory bodies and fewer staff to support them. Nevertheless, as both you and Dr. Herdman have mentioned, incidents such as the Tuskegee syphilis study cast a long shadow over the U.S. biomedical enterprise. The length of this shadow is testament to the need to account for bioethical considerations in public policy decisionmaking.

Again, thank you for the invitation. I would be happy to answer any questions.

The CHAIRMAN. Thank you very much. Excellent comments.

[The prepared statement of Ms. Nishimi follows:]

### PREPARED STATEMENT OF ROBYN Y. NISHIMI

Mr. Chairman, members of the committee, and Senator Hatfield, I appreciate the opportunity to appear before you today to discuss the Office of Technology Assessment's (OTA) background paper, Biomedical Ethics in U.S. Public Policy. As you are aware, Congress has had a longstanding interest in the role of bioethics in American governance. Even before the term bioethics was coined in the early 1970s, congressional hearings were held to establish a National Commission on Health Science and Society, which, had it been established, would have examined the "social and moral" implications of biomedical advances. Since those hearings, held in 1968, Congress has established three bodies to address ethical issues in biomedical research and medical innovation.

#### SCOPE OF THE REPORT

As you requested, OTA reviewed the history of each of these three bodies: the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission); the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (President's Commission); and the Biomedical Ethics Advisory Committee (BEAC). OTA also examined the Ethics Advisory Board (EAB), which was created by the then Department of Health, Education, and Welfare in response to a recommendation of the4 National Commission (table 1). The OTA report identifies the lessons that can be learned from these initiatives in order to provide Congress with background material on the form a new Federal bioethics body could take.

The report also examines two State initiatives: the New York State Task Force on Life and the Law, which is still operational, and the new Jersey Commission on Legal and Ethical Problems in the Delivery of Health Care, which operated for 5 years but currently is unfunded. Finally, the report summarizes bioethics activities in over 50 countries or multinational organizations (table 2). In the past few years, although government-sponsored bioethics entities have disappeared in this country, they have flourished elsewhere. The governments of at least 27 nations on 6 continents have established a national commission of some type or currently have legislation pending to do so. Additionally, multinational organizations (e.g., the European Community, European Parliament, and World Health Organization) also have begun to analyze bioethical issues via committees or commissions.

#### LESSONS FROM THE PAST

The appeal of a federally-sponsored focus for bioethics has waxed and waned over the past two decades. For nearly 4 years—the longest period of time since bioethics burgeoned as a discipline—the Federal Government has been without a formal forum that addresses bioethical issues. In fact, a fully operational body has not existed in over a decade.

Even without a formal Federal effort, however, bioethics has been incorporated into selected public policy analyses. Several OTA reports, for example, included bioethical analyses. And, for issues related to the Human Genome Project, the National Institutes of Health (NIH) and the U.S. Department of Energy (DOE) each fund an Ethical, Legal, and Social Issues (ELSI) grants program. However, both the programs and and the joint ELSI Working Group that advises NIH and DOE lack a formal mechanism to convey ELSI-funded research findings directly into the policy process.

Additionally, despite the lack of a Federal forum, State, local, and private initiatives have developed. Such a widespread, pluralistic approach has advantages over a single national commission. It fosters diversity; no issue becomes captive to any central authority. There are pitfalls attendant to centralization, including a tendency to lose flexibility in interpretation, diffusion arising from forced consensus, and the potential for capture by political interests.

Still, the diversity in bioethics organizations—while bringing the debate to the State, local, or institutional level—cannot always succeed in addressing areas that require expansive access to information and expertise. Centralization brings authority to a process that is rarely achieved with decentralization. A Federal effort generally can call on greater resources than private or State organizations. It also carries cachet, as well as nationwide power to gather data, convene meetings, generate relevant analyses, and invite testimony. The process by which this background paper was produced demonstrates this value: Though allocated a limited budget and a short timeframe, our project gathered responses from around the world—of workshop participants, survey respondents, interviewees, and reviewers—that were rapid and impressive because it was an effort on behalf of the U.S. Congress.

Of the four entities OTA reviewed, we found general consensus that the first three—the National Commission, the President's Commission, and the EAB—were successful, though in the case of the latter, some believed its tenure too short to judge. The fourth effort, BEAC, was deemed a failure.

Many factors—tangible and intangible—contributed to an effort's success. Timing and personalities were important, but were difficult to predict beforehand. Nevertheless, several themes that persist across the success stories were notably absent from BEAC. As might be expected, adequate staffing and funding improved the chance of success. Successful commissions were relatively free of political interference, had flexibility in addressing issues, were open in their process and dissemination of findings, and were comprised of a diverse group of individuals who were generally free of ideology and who had wide ranging expertise.

## PROSPECTS FOR THE FUTURE

In devising a strategy for addressing bioethical issues in a national policy context, OTA identified three basic types of organizational models that should be considered if Congress decides to create a new, broad-based bioethics commission or panel:

—continuous/standing,
—term-limited, and
—ad hoc.

OTA also identified two general groups of issues for which bioethical analyses have been applied: One, specific classes of, or protocols in, biomedical or behavioral research involving human subjects, and two, broad-based issues related to medical practices, health care, or the social implications of research. In fact, the scope and issues Congress believes a commission must address could decide the type of policy body that would be most appropriate to establish.

For example, OTA concurs with the National Commission's recommendation that a standing body is appropriate to consider the ethical implications of certain protocols or classes of federally funded research. In fact, EAB, established by departmental regulation, was intended as a standing body for such purposes after the National Commission concluded its work in 1978. But in 1980, the Department of Health and Human Services (DHHS) disbanded EAB at the direction of the Office of Science and Technology Policy. In doing so, DHHS violated, and continues to be in violation of, its own regulations that govern the protection of human subjects involved in biomedical and behavioral research. A term-limited body could attend to the types of issues that were the focus of most reports produced by the President's Commission, i.e., broad-based topics arising from Federal activities or interest in medicine, health care, or research. Finally, ad hoc bodies can be convened for with narrow or broad-based topics, but OTA found consensus that ad hoc initiatives are the least desirable mechanism to address bioethical dilemmas.

Regardless of the type of organizational model that might be chosen, OTA identified six factors that will be important to the success, or failure, of any new bioethics commission:

—budget, including staffing;
—the charge (i.e., mandate and flexibility to control the agenda);
—appointment process;
—bureaucratic location;
—target audience(s); and
—reporting and response requirements.

OTA excluded politics as a factor per se because the very nature of creating a new entity would subject each factor to the pressures inherent in the political process.

With respect to these six factors, OTA points out that an inadequate or ill-suited approach in any single area can undermine the successful implementation of a new commission, board, or panel. In fact, a deficiency in a single aspect—e.g., funding or the appointment process—can doom an effort to total failure. Table 3 summarizes the key findings related to each factor.

Finally, OTA estimates a new bioethics board or commission would require from $744,000 to $1,920,000 annually, depending on the type of body that is created and the scope of its work.

## SUMMARY

Mr. Chairman, past bioethics efforts have been varied, innovative and largely successful, but they have not endured. In only two decades, U.S. bioethics commissions have had lasting, measurable impacts. Federal regulations to protect human research subjects owe their existence in their current form to the National Commission. The President's Commission's work on patient directives on life-sustaining treatments shaped public debate in health care settings, legislature, and courts.

As the 21st century approaches, Congress faces policy dilemmas that require decisionmakers to understand bioethical considerations, as well as legal or economic dimensions. Furthermore, situations that demand ethical analysis are likely to arise with greater frequency and urgency. At present, no federally-sponsored policy forum exists for generally analyzing ethical issues associated with biological research and new medical technologies.

Today, as Congress considers whether to create a new Federal bioethics body, it can look to the history of governmental involvement in bioethics for a wealth of experience and information. The issue facing Congress is how best to incorporate bioethical analyses into policy decisionmaking. It is a task made especially difficult as fiscal realities mean fewer Federal advisory bodies and fewer staff to support them. Nevertheless, as Dr. Herdman has mentioned, incidents such as the Tuskegee syphilis study cast a long shadow over the U.S. biomedical enterprise. The length of this shadow is testament to the need to account for bioethical enterprise. The length of this shadow is testament to the need to account for bioethical considerations in public policy decisionmaking.

OTA appreciates the invitation to discuss this important topic, and I will be happy to answer any questions.

Table 1--Broad-Based Federal Policy Bodies in Biomedical Ethics

| Year | Initiative | Locus | Number of members | Number of reports | Number of staff |
|---|---|---|---|---|---|
| 1974-78[a] | National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research | Department of Health, Education, and Welfare | 11 | 10 | 16 |
| 1978-80[b] | Ethics Advisory Board | Department of Health, Education, and Welfare | 11 | 4 | 8 |
| 1978-83[c] | President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research | Independent executive branch commission | 11 | 10 | 20<br>(average) |
| 1985-89[d] | Biomedical Ethics Advisory Committee | Congress | 14 | 0 | 2 |

[a] Public Law 93-348 ( 202, 88 Stat. 342, 1974) created the National Commission in July 1974. Commissioners' terms did not rotate.

[b] With reorganization of the Department in 1980, EAB became part of the current of U.S. Department of Health and Human Services. Although disbanded in 1980, current DHHS regulations provide for the existence of an EAB (45 CFR 46.204). In fact, efforts to reestablish and recharter an EAB (53 FR 35232) stalled in 1988 (53 FR 35232). Membership was designed to rotate, and staffing also included consultants and student assistants not included here.

[c] Public Law 95-622 (42 U.S.C. Ch.6A) authorized creation of the President's Commission in November 1978 and set its termination for December 1982; Public Law 97-377 extended this date through March 1983. Due to delays in appointments and funding, the President's Commission was actually operational for just over 3 years. Commissioners' terms rotated, with 21 different individuals serving. Similarly, 30 to 40 people staffed the effort, but generally only 20 at any given time.

[d] In reality, the Biomedical Ethics Advisory Committee (BEAC) functioned for approximately 1 year. Public Law 99-158 established BEAC in May 1985. It was overseen by the Biomedical Ethics Board (BEB), which was comprised of Members of Congress. Almost a year elapsed before BEB was appointed and then nearly 2 1/2 more years before BEAC was constituted. Membership was intended to rotate, and sufficient funds for 12 staff initially were appropriated.

SOURCE: Office of Technology Assessment, 1993.

Table 2 — Typology of International Bioethics Commissions[a,b,c]

| | National commission | Other government commission | Hospital | Professional | Academic | Private |
|---|---|---|---|---|---|---|
| Argentina | 1[d] | | Y | | Y | Y |
| Australia | 1 | [e] | Y | Y | Y | Y |
| Austria[f] | | | Y | | Y | |
| Belgium | [d] | [e,g] | Y | Y | Y | |
| Botswana | | | | | | Y |
| Brazil | 1 | | Y | Y | Y | |
| Canada | 2 | [e,g] | Y | Y | Y | |
| Chile | | | Y | Y | Y | Y |
| China | [d] | [g] | | | Y | Y |
| Columbia[h] | | [i] | | Y | Y | Y |
| Croatia | | [i] | Y | | Y | |
| Cyprus[f] | [d] | | | Y | | |
| Czech Republic | 1 | [e] | Y | | | |
| Denmark | 2 | [e] | Y | | Y | |
| Egypt | | | | | Y | |
| Finland | 2 | | | | Y | |
| France | 1 | | Y | Y | Y | Y |
| Germany[j] | | [g,j] | | Y | Y | |
| Ghana[k] | | | | Y | Y | |
| Greece | 1 | | Y | Y | Y | Y |
| Holy See[f] | | [l] | Y | | | |
| Hungary | 2 | | Y | Y | Y | |
| Iceland | | | Y | Y | | |
| Ireland[f] | | | Y | | | |
| Israel | 2 | | | Y | Y | Y |
| Italy | 2 | [e,g] | Y | Y | Y | Y |
| Japan | | [g] | Y | | Y | Y |
| Kuwait[m] | | | | | Y | |
| Liechtenstein[f,n] | | | | | | |
| Luxembourg | 1 | | | | | |
| Malta | 1 | [e] | | | Y | |
| Mexico | 1 | | Y | | Y | Y |
| The Netherlands | 2 | | Y | Y | Y | Y |
| New Zealand | 1[d] | [g,o] | Y | Y | Y | |
| Norway | 3 | | | | Y | Y |
| Peru | | | Y | Y | | |
| The Philippines[p] | 1 | | Y | | Y | |
| Poland | 3 | | Y | | Y | |
| Portugal | 1 | | Y | Y | Y | |
| Romania | | | Y | Y | Y | |
| Russia | 1 | | | | Y | Y |
| Scotland[q] | | | Y | | | |
| South Africa | | [r] | | Y | Y | |
| Spain | | [g,f] | Y | Y | Y | Y |
| Sweden | 1 | [g] | Y | Y | Y | Y |
| Switzerland | | [g] | Y | Y | Y | Y |
| Turkey | 1[d] | | Y | Y | Y | |
| United Kingdom | | [g] | Y | Y | Y | Y |
| United States | | [e,g] | Y | Y | Y | Y |
| Uruguay | | | Y | Y | Y | |

[a] Unless otherwise indicated, information is based on OTA survey of international government officials and bioethics experts. However, because survey responses varied widely, this table likely represents an incomplete picture of activities in the area of hospital, professional academic, and private entities. Hence, conclusions should not be drawn about absences for any particular entry.

[b] Numbers under the "National commission" column indicate how many federally sponsored entities currently exist to examine either bioethical issues, generally, or research-related issues, specifically. "Hospital" refers to hospital ethics committees or research ethics boards. "Professional" refers to subcommittees within or between professional groups, such as medical or nursing associations. "Academic" refers to departments or curricula in medical schools or other academic institutions. "Private" refers to private organizations devoted to the study of bioethics, excluding professional or academic groups. "Y" indicates these activities in a country.

[c] Though no all-encompassing international organization exists, several multinational organizations (e.g., the Council of Europe and the Commission of the European Community) have issued policy statements and sponsored forums for discussing bioethical issues (app. A). In addition, regional bioethics commissions and/or regional private groups have begun to collectively organize (e.g., in Central/Eastern Europe, Scandinavia, and Latin America)

[d] Legislation is pending to create a new, or additional, national bioethics commission.

[e] Local or regional commissions have existed.

[f] S. Le Bris, "National Ethics Bodies," contract document for the Council of Europe, Ad Hoc Committee of Experts on Bioethics, Round Table of Ethics Committees, Madrid, Spain, Mar. 24, 1992.

[g] Ad hoc, topic-specific commissions have existed.

[h] F. Sanchez-Torres, "Background and Current Status of Bioethics in Columbia." *Bioethics: Issues and Perspectives*, S.S. Connor and H.L. Fuenzalida-Puelma (eds.) (Washington, DC: Pan American Health Organization, 1990).

[i] Laws addressing specific bioethical issues have been enacted.

[j] H.-M. Sass, "Blue-Ribbon Commissions and Political Ethics in the Federal Republic of Germany," *Journal of Medicine and Philosophy* 14:465-472, 1989, and D. Wikler and J. Barondess, "Bioethics and Anti-Bioethics in Light of Nazi Medicine: What Must We Remember," *Kennedy Institute of Ethics Journal* 3:39-55, 1993.

[k] J. Hevi, "In Ghana, Conflict and Complementarity," *Hastings Center Report* 19(4):S5-S7, 1989.

[l] Religious leaders have formed committees to discuss bioethical issues.

[m] M. Al-Mutawa, "Health Care Ethics in Kuwait," *Hastings Center Report* 19(4):S11-S12, 1989.

[n] No ethics bodies exist in this country.

[o] The government has commissioned reports from individuals.

[p] L.D. de Castro, "The Philippines: A Public Awakening," *Hastings Center Report* 20(2):27-28, 1989.

[q] D.M. Teppin and F. Cockburn, "Ethics and Ethics Committees HIV Serosurveillance in Scotland," *Journal of Medical Ethics* 19:43-48, 1992.

[r] The government has issued guidelines and reports in bioethics, but not through commissions.

SOURCE: Office of Technology Assessment, 1993.

Table 3--Elements to Consider in Creating a New Bioethics Body: Key Findings

| Factor | Findings |
|---|---|
| Funding | Although each factor is important, funding is foremost. Sufficient funds to hire an adequate number of qualified, professional staff are essential; otherwise the entity is staffed piecemeal or by castoffs. |
| Mandate and agenda setting | The charge should be structured to provide guidance, if not requirements, for the selection of topics. Circumscribing too narrow a function obviates the potential early warning benefit of a body. Drawing too broad a boundary could move a commission to examine issues that Congress or the President have tasked to others. A combination of mandated studies and the opportunity for commissioners and staff to identify emerging issues would appear to maximize the use of talent, time, and money. |
| Appointment process and composition | Diversity in race, ethnicity, gender, and professional experience is a paramount factor in appointing commissioners and staff.<br>Ideology is a destructive criterion in appointing a bioethics committee. |
| Location | Whether a group is located within the agency whose work it reviews or is independent depends on the mandate and client. No clear consensus emerged. |
| Client | The need for autonomy and independence from both congressional interference and mischief from the executive branch is essential. |
| Reporting and response requirements | To whom a group should report its final work, Congress or the executive branch, raises little controversy; what is problematic is injecting politics during the deliberative process.<br>A successful attempt to tackle bioethical issues will be ineffective if the results of the deliberations are censored or poorly distributed.<br>Whether and how the client must respond is key. A forcing clause for accountability of the client to a commission's recommendations can be linked to a body's establishment, although one does not guarantee responsiveness. |

SOURCE: Office of Technology Assessment, 1993.

The Chairman. I know there are several State bioethic bodies. Did you evaluate which ones were particularly good?

Ms. Nishimi. There are really only two broad-based bioethics initiatives at the State level: the State of New Jersey and the New York State task force, which is still operating. So we did look at those two.

The Chairman. How long have they been functioning?

Ms. Nishimi. The New York State task force has been around for about 5 years. The New Jersey task force is currently underfunded, but I believe it was operational for approximately 4 years.

The Chairman. Have they been free from political interference?

Ms. Nishimi. They actually represent two interesting models because the New York State task force holds closed meetings, and they believe that that is important to their success and freedom from political interference.

The New Jersey commission held public hearings and did become politicized, but they felt with the size of the commission, some of the issues that they discuss, and the staffing, it did not interfere with their recommendations or their introducing several reports.

The Chairman. Do you have recommendations how you can keep the board or commission free from political pressures?

Ms. Nishimi. Well, since OTA does not make recommendation, I would not like to offer any. But I think politics would be infused in any stage of the process. It just requires a good-faith effort on everyone's part.

The Chairman. I think the National Commission that was set up in 1974 really was quite free from it.

Ms. Nishimi. The National Commission is held out as the gold standard frequently, yes.

The Chairman. The OTA report examines international bioethics initiatives. Would you comment briefly about which countries you thought had particularly good commissions?

Ms. Nishimi. The United Kingdom is interesting because its commission is privately funded. With the move to privatization, the Nuffield Foundation created the Nuffield Council on Bioethics. That presents an interesting models because the Government essentially treats it as a quasi-governmental body and it is accorded some stature in official circles.

A country like Denmark has two different commissions, one very populist in nature. They have TV shows. They hold Bioethics Days. Then the other has a slightly more academic bent. And France also.

The Chairman. Is this all developed in the report?

Ms. Nishimi. Yes, it is.

The Chairman. Good. Thank you very much. You have been very helpful. We will be drawing on you for guidance as we move along.

Our next panel: Alexander Capron, professor of law and medicine, University of Southern California, former chairman of the Bioethics Advisory Commission.

Susan Tolle, professor of medicine at the Oregon Health Sciences University, a bioethicist and practicing internist involved in the Oregon plan.

Ken Ryan, professor of obstetrics and gynecology, Harvard Medical School, former Chairman of the National Commission and a past member of the Bioethics Advisory Committee.

We are glad to have all of you. Good to see you again.

Mr. Capron, I know you are under the gun on time, so maybe we will start off with you.

## STATEMENTS OF ALEXANDER M. CAPRON, HENRY W. BRUCE UNIVERSITY PROFESSOR OF LAW AND MEDICINE, UNIVERSITY OF SOUTHERN CALIFORNIA, LOS ANGELES, CA; DR. SUSAN W. TOLLE, PROFESSOR OF MEDICINE, AND DIRECTOR, CENTER FOR ETHICS IN HEALTH CARE, OREGON HEALTH SCIENCES UNIVERSITY, PORTLAND, OR, AND DR. KENNETH J. RYAN, DIRECTOR, CENTER FOR ETHICS, BRIGHAM AND WOMEN'S HOSPITAL, BOSTON, MA

Mr. CAPRON. Mr. Chairman, thank you for inviting me to appear before you on the subject of whether to recommend the establishment of one or more governmental bodies that would address the ethical, legal, and social issues that are generated in health care and biomedical and behavioral research. With your consent, I have submitted a statement which I would ask to have published in the record, and I will just summarize my remarks.

As you may recall, I first testified on this subject in hearings you held 20 years ago that led to the National Commission. Having served as a consultant to that Commission, as executive director of the President's Commission, and as Chair of what you described as the ill-fated Biomedical Ethics Advisory Committee, as well as serving on several of those other groups in NIH and OTA which you asked Dr. Nishimi about, I speak today from the sum of these experiences as much as from any analytic, academic perspective.

My conclusion is, indeed, that the United States needs and would benefit from a new commission at the highest level of Government, mandated to report on a broad range of bioethical issues. The task, I think, is to find a means that will satisfy that.

I will briefly touch on three points: the need for a public body, the prospects of benefit, and the characteristics of the body.

Unlike the skepticism that was voiced 25 years ago when then-Senator Walter Mondale first proposed a National Committee on Health Science and Society, I do not think there can be much doubt that biomedical research and health care raise important and difficult issues that need to be addressed in a thoughtful fashion. And as Senator Mondale said at the time, we can assume that the public is going to get involved with those issues, so the question is merely, and I quote, "whether they will be involved in a sophisticated, responsible way, or whether we will be acting out of ignorance or prejudice, because of the absence of a responsible approach."

Our experience with the National and President's Commissions demonstrate how substantial and complex the issues pressing for attention could be. However successful these bodies may have been, they did not end the need for further study. Indeed, in its final report, "Summing Up," the President's Commission noted that it made no claim of either exhausting the range of important concerns that deserve to be addressed or of closing the book on the issues that it had studied. And it pointed in particular to several topics, such as medically assisted reproduction, the control of the aging process, and developments in the neurosciences, that were already worthy of attention even as the Commission was closing its doors.

The decade since then has only added to the list of areas where it would be very useful to be able to turn to a body like the President's Commission for analysis and advice: for example, research on HIV infection and AIDS and the treatment for its victims; the burgeoning techniques of genetic diagnosis and treatment; care for the elderly and demented, particularly those without family or close friends to play the role of surrogate decisionmaker; genome mapping, including studies of large family pedigrees and of isolated aboriginal populations; and a wide range of topics in human subjects research, from the criteria used to identify research areas to pursue to appropriate division of the costs of clinical studies between research sponsors and patients and their insurers.

What all of these areas have in common is that they involve practices that are either not adequately addressed by prevailing norms of science and society or that at least are in tension with these norms. They are, in other words, areas in which disagreements about what is proper and appropriate can be expected to arise and to need careful attention if they are to be resolved in a way that is satisfactory to a large number of people, particularly those with the most immediate stake in a particular area, such as the physicians and patients involved.

With this brief sketch of the need, I will turn to the equally cursory look at the second question: What are the prospects of benefit from a public commission responding to this need? This breaks down into several sub-questions: Why does the body have to be public? If public, why does it have to be a Federal commission? Can a Federal commission provide useful advice?

Organizations of health care professionals and a large number of scholars and bioethics research centers have produced studies and reports that can be a rich source for thoughtful analysis, particularly when they reflect multidisciplinary interaction. Yet such work lacks any necessary claims of public attention or authority. Moreover, to the extent that these efforts are truly scholarly, both their objects and their products may be too esoteric to interest the general public or policymakers, and operating with an official imprimatur, the individual bioethicist or bioethics group will not necessarily be able to gather the factual information from all relevant sources, especially government agencies, or intellectual contributions from the most appropriate individuals.

For all these reasons, the bodies to which we turn for analysis and resolution of the pressing bioethics issues ought to operate with public authorization.

If the body is public, why should it be Federal? After all, as you have just heard, some valuable work has emerged at the State level. But the issues do not stop at State borders, even when they are traditionally matters of State regulation. Further, some of the most important issues—for example, around research and the distribution of health care resources—are decidedly national topics.

As an alternative to any specialized undertaking, perhaps we could leave resolution to the existing agencies, courts, or legislative bodies. But while they will serve ultimately to pass the policy judgments, they need advice beyond what they can generate themselves.

So then the question is will a Federal commission work, and I think from the staff this was where my advice was being particularly sought from my experience.

Looking at that experience over the past 20 years, I believe that it can be said with some confidence that such groups do provide valuable services. Dr. Kenneth Ryan being here, I will not comment on the work of the National Commission more than to say that I think it is a widely held view among experts in the field that the National Commission's reports on its core issues of the principles and practical measures that should guide research with human subjects are very highly regarded and have had enormous practical influence for the good, as you noted, Mr. Chairman, in leading to the regulations throughout the Federal Government.

I obviously cannot speak of the President's Commission work with equal dispassion, but perhaps it would be useful for me to review that work briefly for you. The Commission was authorized in 1978 and instructed to report on six specific and widely divergent topics, including a report required every 2 years on the protection of human subjects—in effect, a continuation of the work of the National Commission.

In the 39 months that followed the swearing-in of the initial group of 11 Commissioners at the White House in January of 1980, the President's Commission held more than 2 dozen meetings, including a number outside Washington. The original Commissioners were replaced, following resignations and term expirations, by a total of 10 new Commissioners. And the Commission, with the help of the staff that numbered about 20 at any one time, prepared, revised, and disseminated 11 reports. Of these two, the "Summing Up" document, which was a precis of the work, and another volume, "Whistleblowing in Biomedical Research," which was really a report of the proceedings at a symposium, are not actual substantive reports, of which there were 9: 6 on mandated topics and 1 one report in response to a request for the President on genetic engineering in human beings, 1 at the request of the Ethics Advisory Board, which was being ushered out of existence at the time, where we took on the subject of compensating for research injuries, and, finally, 1 report, probably our most influential, on life-sustaining medical treatment, which we undertook at our own initiative.

In my written statement, I provide a thumbnail sketch of each report and evaluate its impact. I would conclude that five of the reports had certainly significant impact, in some cases becoming seminal documents in their field and in others leading to substantial changes in law and professional practice. Four reports had less noticeable impact, although in some cases even these have yielded results slowly or have been returned to for advice that some have now labeled prescient.

Almost uniformly, even critics of individual reports have praised the Commission for presenting its findings and conclusions in a fashion that was accessible to the general public, with sufficient specificity to be of use to policymakers and professionals, and with adequate justification in ethical terms. Literally tens of thousands of copies of each of the reports were distributed upon request of the Commission and sold by the Government Printing Office, and my own travels around the country in the past 10 years have given me many occasions to see that these have been frequently passed from hand to hand, dogeared and carefully studied by colleagues seeking to resolve issues, establish policies, and provide education.

Having identified a need and related one set of experiences to show that a Federal commission can fulfill that needs, it remains to describe the characteristics of a body that will lead to success.

First, on the question of mandate, the Commission should have a broad mandate, in my view, at the level of policy and general guidance with no responsibility to review the ethical acceptability of individual protocols, a task that needs to be addressed, however, preferably by a reconstituted Ethics Advisory Board as required by the DHHS regulations. The reason for breadth in the mandate is that the issues inter-relate, and the conclusions that the commissioners reach in one area will make it easier for them to study and resolve subsequent issues, and the existence of an experienced staff will lessen the time and expense required. Furthermore, it is important that they be concerned about the possible implications of their conclusions in one area for other areas, lest they are either unintentionally blinkered in their outlook or willfully parochial.

If the group does a good job in resolving issues, the credibility of its conclusions on subsequent topics will, and should, be enhanced. All of these advantages are lost if the panel is constituted on an ad hoc basis to address a single issue. It is important for Congress to specify a number of issues that seem most in need of attention, but also to permit the commission to add further topics in the general field.

Duration: There are good arguments to be made for either a time-limited or a standing body. Perhaps a "sunset clause" provides the best compromise. It sets an initial date for termination, which provides a goad for productivity, but permits an easy means for continuing the commission if that is merited.

Location and membership: It is on this topic that the three congressionally sanctioned bioethics bodies can usefully be compared. My belief is that the movement between the National Commission and the President's Commission was good in that it produced a group with greater visibility, higher prestige, broader mandate, and more independence; whereas, the movement between the President's Commission and the BEB/BEAC was misguided in that it produced a group more subject to special interest politics and with less independence.

I do not want to overgeneralize from a small sample, but it seems likely that, given the volatility of some issues in bioethics, any arrangement that ties the commission too closely to Congress will result in an appointment process that looks for "balance" in ideological terms and results in a group that is not only potentially polarized but consists of at least some members who regard themselves, and are regarded by others, as "representatives" of the groups or organizations that lobbied for their appointment. Furthermore, a group located too close to Congress does not serve, for your purpose, Mr. Chairman, one of the most useful functions of a commission, which is to permit sensitive topics to be removed from the political arena and considered in a more deliberate fashion during which individuals who started out with differing views are often able to discover a great deal of common ground, as you were discussing with Senator Hatfield, especially once the issue has been refined and the relevant data more fully developed.

Vesting the appointment power in the President, subject to certain categorical requirements to ensure diversity of views and experience, provides Congress and the public with adequate assurance that the intended purposes will be carried out. The power over appropriations further ensures that if the President or the commission itself were to deviate too far from the congressional expectations, the work can be reined in or halted.

Audience and response: The commission should be required to report to the President, to Congress, and to any departments or agencies affected by its recommendations, but these do not begin to exhaust the potential audience for its reports, which may include individuals, as patients or professionals, as well as State legislators and judges and officers of health care institutions.

For those recommendations that are addressed to departments and agencies, action-forcing authority is highly desirable.

Finally, funding and staffing: Depending on the size of the mandate, staff in the range of 20 FTE's and an annual appropriation of about $2 million should be adequate. It is important that the commission receive a direct appropriation to ensure its independent and that it have the right to hire its own staff.

Plainly, there is much more that can be said about "doing ethics in public" through a Federal commission charged to report on the ethical, social, and legal implications of biomedical and behavioral research and practices. I appreciate the opportunity to share these observations with your committee, and I would be pleased to respond to any questions you may have, Mr. Chairman.

Thank you.

The CHAIRMAN. Thank you very much. Your comments have been very helpful.

[The prepared statement of Mr. Capron follows:]

## Prepared Statement of Alexander Morgan Capron

MR. CHAIRMAN, Members of the Committee, and Senator Hatfield: Thank you for inviting me to appear before you today on the subject of "Biomedical Ethics and U.S. Public Policy." Stated in this way, the topic for the hearing is very broad, but I take it that the heart of the question before this Committee is whether to recommend the establishment of one or more governmental bodies that could address the ethical, legal, and social issues that are generated in health care and biomedical and behavioral research. The purpose of my testimony is to explain why I believe you should reach an affirmative answer to this question.

As you know, I do not approach this topic free of bias—or, as I would prefer to see it, innocent of personal experience, having been involved with the three bodies established by Congress in this area. I served as a consultant to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-78), as the Executive Director of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1979-83), and as Chair of the Biomedical Ethics Advisory Committee (1988-90). I am now and have been on a number of the more narrowly focused efforts to address bioethical issues, such as NIH's Recombinant DNA Advisory Committee and its Subcommittee on Human Gene Therapy, the Task Force on Genetic Information and Insurance of the ELSI Branch at the National Center for Human Genome Research, and various panels at the Office of Technology Assessment. It is the sum of these experiences as much as any academic analysis that leads me to conclude that the United States needs and would benefit from a new commission at the highest level of government mandated to report on a broad range of bioethics issues. The task, then, is to find means suited to the objective.

To organize my remarks, perhaps it would be best for me to address the three points I just mentioned, in turn: the need for a public body, the prospects of benefit from such a body, and the characteristics of such a group that I believe would make it best able to provide those benefits. In all of this, I will attempt to substantiate my conclusions by reference to the past federal experience.

## THE NEED

Twenty-five years ago, when then-Senator Walter Mondale first proposed a "National Committee on Health Science and Society" (S.J. Res. 145, 90th Cong., 2d Sess.), the term "bioethics" hadn't yet been coined. At the Senate committee hearings in March 1968, attention was focused on human heart transplantation—which had first been undertaken only months before. And several of the leading physician-scientists who appeared took a dim view of the proposal because they couldn't see any benefit from involving "theologians, lawyers, philosophers, and others," as they put it, in their work. Senator Mondale disagreed because, as he said, we can assume the public will become involved and the question is merely

> whether they will be involved in a sophisticated, responsible way, or whether we will be acting out of ignorance or prejudice, because of the absence of a responsible approach.

Over the next few years, as further biomedical developments arose or were predicted—prenatal diagnosis of genetic disorders, electrical stimulation of the brain, *in vitro* fertilization, and human cloning—he put forward further proposals. The resolution he introduced in 1971, with Senators Kennedy and Pell among its co-sponsors (S.J. Res 75, 92d Con., 1st Sess.), was eventually approved by the Senate as amended on Dec. 2, 1971, but not passed by the House.

While the ethical and social issues associated with biomedical developments of this type were not compelling enough to convince Congress to establish a national body, the sense of outrage and alarm generated by several instances of unethical biomedical research were. In the wake of the revelations of the Tuskegee Syphilis Study and of experiments on inmates in prisons and mental hospitals, the Health Subcommittee of your Committee on Labor and Public Welfare held 10 days of hearings between February and July 1973 on how the promising fruits of biomedical research could be harvested and used in an ethical fashion. By that time, I suspect that none of us who testified—and none of those such as the Chair and Senator Pell who asked the question—had any doubt that the Nation needed a means to provide a thorough-going examination of research with human subjects. The result, of course, was Title II of the National Research Act of 1974, which among other things established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission). That group did an excellent job of addressing, clarifying, and even resolving many of the central issues in human subjects research; its recommendations provide the core of the regulations that now govern biomedical and behavioral research with human subjects at institutions supported by all federal departments and agencies.

I think it is generally agreed that the National Commission did a less adequate job of addressing "the ethical, social, and legal implications of advances in biomedical and behavioral research and technology," the so-called "Special Study" assigned to it based on Senator Mondale's earlier resolutions (Pub. L. 93-348, Sec. 203). The problem lay not in the topic itself but in its being outside the main area—human subjects research—to which the Commission was devoted. The need for an examination of this broader terrain only became more acute and obvious during that period, however. Therefore, it was not surprising that when the National Commission completed its work in 1978, the Congress decided to create a new commission with government-wide jurisdiction and with a mandate to examine issues in medical practice and healthcare delivery as well as in research.

In a few moments I will attempt a quick review of the work of that group—the President's Commission for the Study of Ethical Problems in Biomedical and Behavioral Research (President's Commission). However successful its reports were, it did not end the need for further study. Indeed, in its final report, *Summing Up*, the Commission noted that it made no claim "of either exhausting the range of important concerns that deserve to be addressed or of closing the book on the issues it has studied" (p. 84). And it pointed in particular to several topics (such as medically assisted reproduction, control of the aging process, and developments in the neurosciences) that wer already worthy of attention even as the Commission was closing its doors. The decade since then has only added to the list of areas where it would be very useful to be able to turn to a body like the President's Commission for analysis and advice: research on HIV infection and AIDS and treatment for its victims; the burgeoning techniques of genetic diagnosis and treatment; care for the elderly and demented, particularly those without family or close friends to play the role of surrogate decisionmaker; genome mapping, including studies of large family pedigrees and of isolated aboriginal populations; and a wide range of topics in human subjects research, from the criteria used to identify research areas to pursue (particularly relevant to research touching on the health of women, minorities and children) to appropriate division of the costs of clinical studies between research sponsors and patients and their insurers. What all of these areas have in common is that they involve practices that are either not adequately addressed by the prevailing norms of science and society or that at least are in tension with those norms; they are, in other words, areas in which disagreements about what is proper and appropriate can be expected to arise and to need careful attention if they are to be resolved in a way that is satisfactory to a large number of people, particularly those with the most immediate stake in the particular area (such as the physicians and patients involved).

## THE PROSPECT FOR BENEFIT

With this brief sketch of the need, let us turn to an equally cursory look at the second question: what are the prospects of benefit from a public commission responding to this need? This breaks down into several sub-questions: why does the body have to be public? If public? does it have to be a federal commission? can a federal commission provide useful advice?

### WHY PUBLIC?

Topics of the type I've just mentioned are clearly important and timely. Thus, it is hardly surprising that even in the absence of a federal commission, the questions have not gone unattended. Professional groups—such as the American Fertility Society, the American College of Physicians, and the American Academy of Pediatrics—have formed ethics committees to address these issues. All such efforts are to be lauded, but even when they produce thoughtful conclusions, they are likely to be of limited value or effect precisely because the issues transcend the competence or authority of any profession. Indeed, at the heart of the field of bioethics has been the premise that the issues involved cannot be left to biomedical professionals in a democratic society based upon the worth and autonomy of each person. Even when professional groups reach out—such as through the Joint Committee on Biomedical Ethics of the Los Angeles County Medical Association and Los Angeles County Bar Association, or the National Advisory Board on Ethics in Reproduction (NABER) sponsored by the American College of Obstetrics and Gynecology—their work can contribute to the resolution of these issues but cannot claim to be a substitute for a publicly sanctioned process.

Likewise, the growth of bioethics as a field of research and teaching has led not only to the production of many people who formally identify themselves as "bioethicists" (as opposed to those of us who just stumbled into the field and who tend to see it as inherently interdisciplinary), but has also resulted in a flood of scholarly writing by individuals and collaborative documents under the auspices of the many bioethics centers across the country. Again, this work can be a rich source for thoughtful analysis and has the advantage of coming from outside the professions involved, often indeed with an multi-disciplinary background. Yet, like the work of the ethics bodies within professional associations, it cannot pretend to speak with any public authority. Moreover, to the extent that these efforts are truly scholarly, both their objects and their products may be too esoteric to interest the general public or policymakers, and, operating without an official imprimatur, the individual bioethicist or bioethics group will not necessarily be able to obtain factual information from all relevant sources (especially within government agencies) or intellectual contributions from the most appropriate individuals.

For all these reasons, the bodies to which we turn for analysis and resolution of the pressing bioethical issues ought to operate with public authorization. Such authority bestows exceptional powers to gather relevant data and analysis (derived both from statutory authority and simply from its prominence in the field), just as it also carries special responsibilities to reach out widely to learn the full range of informed opinion within society, to weigh such information in an open and thoughtful manner, and to fashion its results in a way that respects the fundamental values of the society. As the President's Commission concluded in *Summing Up*:

> In a pluralistic society, a commission on bioethical issues can serve as more than a forum for the airing of differences on matters of concern, and more even than as a catalyst to force a closer look at the unexamined ways that health care decisions have traditionally been made. It can also articulate the broad area of agreement that already exists in this country on most of the issues at stake—and it can, if it is fortunate, provide the means for enlarging the field of common agreement and for reassuring those who daily face the challenges of making bioethical decisions as patients, professionals, or public servants. Finally, a commission on bioethics can play an important part in engendering and encouraging the process by which a vibrant and ever-developing society reexamines, revises, and reaffirms its system of values and belief—a system in which the issues of medicine and research are significant but not alone.

## WHY A FEDERAL COMMISSION?

If one agrees that matters of the importance we are talking about here need examination by a public body, in addition to any scholarly, professional, or other private bodies, need that group be a federal commission? Certainly, we have seen some substantial value emerge at the state level, both from broadly based grass roots groups (loosely configured into the American Health Decisions movement) and from officially established groups (such as the New York State Task Force on Life and the Law). Yet the issues are obviously ones that don't stop at state borders, even when they are traditionally matters of state regulation, such as in family law and the licensing of healthcare professionals. Further, some of the most important issues—for example, around research and the distribution of healthcare resources—are decidedly national topics. Thus, while state efforts are valuable —both in addressing topics that have not been resolved nationally and in implementing the national resolution with a sensitivity to local circumstances—they are no substitute for the national process.

An alternative to any specialized undertaking in this field would be to leave resolution of the issues as they arise to existing institutions. Without a doubt some issues are going, for example, to be presented during the course of litigation and will therefore become the subject of judicial resolution. Yet it is remarkable how frequently courts (both state and federal) have included in their decisions in these cases (involving, typically, issues of death and dying and issues of assisted reproduction) a heartfelt plea for guidance from others; where such pleas have been less noticeable is precisely in those areas where past efforts by groups like the National and President's Commissions have provided just the sort of guidance the courts needed.

Often, the courts have looked to the legislature for guidance. And on both the state and federal levels it is apparent that many of these bioethics issues may need to be addressed through formal law-making, either by statute or by the rule-making authority delegated by statute to executive departments and agencies. Thus, any national commission cannot be expected to be a substitute for such existing bodies. But neither are such bodies a good substitute for commissions of the sort that have operated in this field. Simply put, as you well know, Congress and its committees are already overwhelmed by the need to resolve countless acute issues. Furthermore, the inherently political atmosphere of the legislative process, with the demands of constituency groups and special interests, may force polar positions where under other circumstances a large body of agreement exists.

Given the pressures of time for legislators and their staff, opportunities for extended analysis of a subject, along with broad canvasing of public and scholarly opinion, are few and far between. This is true of the executive branch as well. For example, the Recombinant DNA Advisory Committee (RAC) at the National Institutes of Health responded to the recommendations of the President's Commission in its report *Splicing Life* by establishing the

Human Gene Therapy Subcommittee to provide a means of reviewing proposals involving the use of recombinant DNA techniques on human beings and to continue to explore the issues that would be posed by the extension of these techniques into genetic enhancement and germ-line gene therapy. Yet, although developments in gene therapy have been so important that the RAC has absorbed the work of the Subcommittee, the demands for review of protocols involving gene transfer experiments have been so unrelenting that the RAC has had no time for several years to give even the most cursory attention to the larger (and perhaps more troubling) issues of genetic enhancement and germ-line therapy.

## WILL A FEDERAL COMMISSION WORK?

If the sum of what I have said thus far is that we need a public body, that this body should be at the national level, and that existing mechanisms (the courts, Congress) are not adequate for the task at hand, can we say with any confidence that such an approach will work? Perhaps, when the Chairman held the hearings on human experimentation in 1973 and then crafted the National Commission to respond to the problems that had been uncovered, there might have been reason for doubt on this subject. But with the experience of the past twenty years, I believe that it can be said with confidence that such groups can succeed in exactly the ways that we need. Since Dr. Kenneth Ryan, who chaired the National Commission, is also testifying today, I need do nothing more than to provide what I believe to be the widely held view among experts in the field that the National Commission's reports on its core issue of the principles and practical measures that such guide research with human subjects are very highly regarded and have had enormous practical influence for the good.

I cannot speak about the President's Commission with equal dispassion, but perhaps it would still be useful for me to review its work briefly. The Commission was authorized in 1978 and instructed to report on six specified and widely divergent subjects (including a required report, every two years on the protection of human subjects—in effect, a continuation of the National Commission's work). In the 39 months that followed the swearing in of the initial group of 11 Commissioners at the White House in January 1980, the President's Commission held more than two dozen meetings, including a number outside Washington, D.C.; the original Commissioners were replaced, following resignations and expirations of terms, by a total of 10 new Commissioners; and the Commission, with the help of a staff that numbered about 20 at any one time prepared, revised, and disseminated eleven reports. One of these reports that I've already mentioned, *Summing Up*, was primarily a precis of the other reports, though it also provided the Commission's response on one of its mandated subjects (privacy and confidentiality regarding research subjects and patients). Another volume, *Whistleblowing in Biomedical Research*, is actually the proceedings of a symposium on that subject co-sponsored by the Commission, rather than an official report. Thus, the Commission's work consisted of nine reports: six on mandated topics (including two "biennial reports" on human subjects research), one in response to a request from the President, through his Science Advisor (on genetic engineering in human beings), one (on compensating for research injuries) in response to a request from the Ethics Advisory Board, which was ushered out of existence just as the President's Commission was beginning its work, and one (on life-sustaining medical treatment) on its own initiative, pursuant to a clause in its authorizing statute. What should one make of those nine reports in terms of their usefulness and influence? Let me provide a thumbnail sketch, dividing the reports between those of substantial and those of more modest impact, and recognizing in all cases that I am assessing them as public documents, intended to have an influence on policies and practices and not as academic documents, to be evaluated primarily in scholarly terms.

Substantial Impact

*Defining Death* (1981): This report set forth the Uniform Determination of Death Act (UDDA), which resulted from a collaboration among the Commission, the American Medical Association, the American Bar Association, and the National Conference of Commissioners on Uniform State Laws; it provided the scientific and philosophical explanations for the statute, and related the statute to clinical experience; and it was accompanied by a set of medical guidelines for the determination of death signed by nearly all the leading neurologists, neurosurgeons, and other physicians with relevant expertise on the subject. Since this report, the UDDA or its equivalent has been enacted in every state in the country, and the standards established by the medical consultants are the prevailing ones for the determination of death nationally.

*Deciding to Forego Life-Sustaining Treatment* (1983): This report is probably the most widely known and most frequently cited (in court decisions and legislative deliberations as well as scholarly articles); it provided clear guidance for patients, physicians, and healthcare facilities on considerations in making decisions about critically ill and dying patients; it recommended expanded use of advance directives, with special emphasis on the then-new idea of durable powers of attorney for health care. Since the report, the Commission's report has been extensively reprinted and used in many educational settings for healthcare professionals and the public; most hospitals have established committees and other means of getting ethical consultation in difficult cases involving life-sustaining treatment; all states have adopted some form of advance directive legislation; and the report has been heavily relied upon in judicial opinions, including the *Cruzan* case, the Supreme Court's one decision in this field.

*Splicing Life* (1982): This report grew out of concerns expressed by religious leaders that dangerous and ethically questionable uses of genetic engineering were soon going to be applied to human beings; the report divided therapeutic uses of recombinant techniques (for example, between somatic cell and germ-line manipulations) and sorted out the different issues each type raised; besides indicating situations that did not raise unusual concerns, it recommended various means of dealing with the issues. The report was the subject of three days of hearings by a House subcommittee; it resulted in the creation of the Human Gene Therapy Subcommittee of the RAC (at NIH), which developed guidelines and procedures for reviewing and approving gene therapy experiments (which might otherwise have been subject to ad hoc attacks and interference); the report also led to the proposal by then Rep. Albert Gore, Jr., for a presidential commission on genetic therapy, which was later expanded into the statute that established the Biomedical Ethics Board.

*Securing Access to Health Care* (1983): This mandated subject took the Commission further outside the range of subjects addressed up to that time by bioethicists; it provided data showing the extent of non-coverage or inadequate health insurance coverage in the country and the clinical and personal effects of this gap; eschewing the much debated terminology of "a right to health care," the report built the ethical case for the conclusion that society has an ethical obligation to ensure access to an adequate level of care for all without imposing undue burdens on anyone. The Commission's conclusions were quickly picked up both in the popular press and in the work of health services researchers and health economists and have become the starting point for present debate (the question being, in judging the ethics of competing proposals: how well do they move society toward meeting its ethical obligation?); furthermore, the conclusions have been specifically influential in a number of state efforts (such as in Oregon) to extend health care to all residents.

*Protecting Human Subjects* (1981): The first biennial report on the regulation of research with human subjects addressed a number of discrete issues (including the failure of the Department of Health and Human Services to respond to several recommendations of the National Commission) and also recommended that the Federal government adopt a uniform set of regulations across the more than twenty departments and agencies that supported research utilizing human subjects. Although it took nearly a decade, the uniform federal rule was finally promulgated several years ago.

Modest Impact

*Screening and Counseling for Genetic Conditions* (1983): This report reviewed the history of, and growing possibilities for, genetic screening and its implications for health care and patient welfare, as well as the role of genetic counseling, with and without screening; it set forth and applied a series of ethical principles; and it examined the special issues that would arise once it became possible to screen for a fairly common deleterious gene, using cystic fibrosis as an example. At the time of its issuance, the report had influence primarily among genetic counselors, but it received much less attention than other reports and, as the Commission went out of business shortly after issuing the report, there was little opportunity for follow-through to bring the conclusions to the attention of relevant physicians, scientists, and policymakers; nonetheless, six or seven years later, as the initial screening tests became available for cystic fibrosis, all of the issues predicted by the Commission came into focus and the relevant professional organizations and public bodies began looking to the Commission's work for guidance. .

*Making Health Care Decisions* (1982): This report was among the most extensively researched and scholarly of the Commission's work, providing original studies on public and professional understandings of the obligations of physicians to make candid disclosures of information and otherwise to communicate with their patients, as well as philosophical analysis of these obligations and explanation of their manifestation in the law of "informed consent." Although the report has been well received and relied upon in the scholarly literature, it has had relatively little influence on the development of public policy, outside of some direct and indirect effect on judicial lawmaking about informed consent.

*Compensating for Research Injuries* (1982): This report addressed a subject that had been studied by two previous groups within the Department of Health, Education, and Welfare, but on which no action had been taken; the Commission found that the data on research injuries were too inadequate to reach conclusions on whether a system of compensation should be mandated or exactly what form it should take; nonetheless, since the Commission found that such compensation would be ethically desirable under certain circumstances, it set forth a recommended design for an experimental system of compensation, intended to test both the need for and feasibility of formal compensation systems. The Department and the National Institutes of Health never undertook the recommended experiment, although they did mandate that research institutions disclose their policies about compensation as part of the information provided to potential research subject; the issue remains a matter of concern to many commentators, although in the absence of a signal case or event, it seems unlikely that action will be taken; again, the closing of the Commission left no body in place to follow up on the report and press the Department for action (as the President's Commission had been able to do for certain recommendations of the National Commission).

*Implementing Human Research Regulations* (1983): The second biennial report on human subjects protection, like the first, was primarily addressed to the federal officials charged with implementing regulations in this field; the heart of the report dealt with the need to develop means to ensure that Institutional Review Boards (bodies mandated by the National Research Act of 1974 and by federal regulations to provide prior review of research protocols at institutions receiving federal research funds) were carrying out their responsibilities satisfactorily; the Commission reported on a method of peer site visits that it had developed and field-tested with good results, as one possible way to address this problem. Although the relevant governmental agencies (principally, the Department of Health and Human Services) have yet to implement the suggested site visits or other means of monitoring IRBs routinely, a study has recently been commissioned from a research consortium on the effectiveness of IRBs;

thus, the report has had some impact on its addressees, but it remains largely invisible to the larger community, particularly as a consequence of its issuance shortly before the Commission closed.

In my calculations, this means that five reports had measurable impact, in some cases becoming seminal documents in their field and in others leading to substantial changes in law and professional practice; four reports had less notable impact, although in some cases even these have yielded results slowly or have been returned to for advice that some have even labeled "prescient." I should emphasize, that even when reports have had substantial influence they may also have produced vigorous debate and dissent. In particular, despite the acceptance of the statutory standards and clinical guidelines for determining death by the public and physicians alike, a number of philosophers remain convinced that a "higher brain" standard is more defensible than the "whole brain" position advocated by the Commission. Likewise, the report on access to care has been attacked by those who favor a rights-based approach to health care and who found the societal obligation articulated by the Commission unconvincing. Almost uniformly, however, even critics have praised the Commission for presenting its findings and conclusions in a fashion that is accessible to the general public, with sufficient specificity to be of use to policymakers and professionals, and with adequate justification in ethical terms. Literally tens of thousands of copies of the reports were distributed upon request by the Commission and sold by the Government Printing Office, and my own travels around the country in the past ten years has given me many occasions to see that these have frequently been passed from hand to hand and carefully studied by many colleagues seeking to resolve issues, establish policies, and provide education.

## CHARACTERISTICS

Having identified a need and related one set of experiences to show that a federal commission can fulfill that need, it remains for me to describe the characteristics of such a body that I believe will best ensure its success. In this, I will also draw on my experiences with the ill-fated Biomedical Ethics Advisory Committee, mostly by way of caution on some features that I believe are best avoided in such a group.

### Mandate

The commission should have a broad mandate at the level of policy and general guidance, with no responsibility to review the ethical acceptability of individual projects (a task that needs to be addressed, preferably by reinstating the Ethics Advisory Board, as required by DHHS regulations). The reason for breadth in the mandate is that the issues inter-relate and the conclusions the group reaches in one area will make it easier for them to study and resolve subsequent issues, and the existence of an experienced staff will lessen the time and expense required; furthermore, it is important that they be concerned about the possible implications of their conclusions in one area for other areas, lest they be either unintentionally blinkered in their outlook or wilfully parochial. If the group does a good job in resolving issues, the credibility of its conclusions on subsequent topics will—and should—be enhanced. All of these advantages are lost if the panel is constituted on an ad hoc basis to address a single issue. It is appropriate to specify a number of issues that seem to Congress most in need of attention, but to permit the commission to add further topics in the general field, as its time and resources allow and as dictated by the urgency and importance of such additional topics.

### Duration

There are good arguments to be made for a time-limited body; as the experience of both the National and President's Commissions indicates, the existence of a date by which the work had to be completed resulted in a high level of productivity; furthermore, there is danger that a standing commission (or its staff) might become overly bureaucratic in its approach to its work. On the other hand, arguments similar to those made regarding mandate would favor the existence of a standing body (with staggered terms for members), on grounds of efficiency, consistency, and credibility. Perhaps a "sunset clause" provides the best compromise: it sets an initial date for termination, but permits an easy means for continuing the commission if its work and the issues still to be address merit an extension.

### Location and Membership

It is on this topic that the three Congressionally sanctioned bioethics bodies can usefully be compared. My belief is that the movement between the National Commission and the President's Commission was good in that it produced a group with greater visibility, higher prestige, broader mandate, and more independence, whereas the movement between President's Commission and the BEB/BEAC was misguided in that it produced a group more subject to special interest politics and with less independence. I do not want to over generalize from a small sample, but it seems likely that given the volatility of some issues in bioethics, any arrangement that ties the commission too closely to Congress will result in an appointment process that is looks for "balance" in ideological terms and results in a group that is not only potentially polarized but that consists of at least some members who regard themselves (and are regarded by others) as "representatives" of the groups or organizations that lobbied for their appointment. Furthermore, a group located too close to Congress does not serve one of the most useful functions of a commission, which is to permit sensitive topics to be removed from the political arena and considered in a more deliberate fashion during which individuals who started out with differing views are often able to discover a great deal of common ground, especially once the issue has been refined and the relevant data more fully developed.

Vesting the appointing power in the President, subject to certain categorical requirements to ensure diversity of views and experience, provides Congress and the public with adequate assurance that the intended purposes will be carried out; the power over appropriations further ensures that if the President or the commission itself were to deviate too far from Congressional expectations, the work can be reined in or halted. If the commission has a limited term, then the value of continuity and the "learning curve" favor a fixed membership; if the group is constituted as a standing body (subject to "sunset clause" periodic review and renewal), then a rotating membership, with staggered terms, seems advisable, in part as a means to ensure diversity of views and avoid bureaucratic narrowing of the group's collective vision.

### Audience and Response

The commission should be required to report to the President, to Congress, and to any departments or agencies affected by its recommendations, but these do not begin to exhaust the potential audience for its reports. Some of the topics addressed will be suitable for federal legislation or regulation, but not all; for some, recommendations and findings may be of importance to individuals, as patients or professionals, as well as to state legislators or judges or as officers of healthcare institutions. The commission should be free to address topics of interest to all these groups, although it must also be careful not to slip into producing documents that are solely of intellectual or academic interest, with no practical application at any level.

For those recommendations that are addressed to departments and agencies, action-forcing authority is highly desirable. Of course, as the experience of both the National and the President's Commissions demonstrates, such authority is not self-executing, and agency officials who want neither to act nor to explain their inaction may sometimes disregard the statutory requirements, which is especially easy for them to do if the commission is no longer in existence.

Funding and Staffing

Depending on the size of the mandate, staff in the range of 20 FTEs and annual appropriations of about $2 million should be adequate. (The President's Commission was authorized for $5 million per year for four years; in operation, it expended under $5 million over its entire lifetime.) It is important that the commission receive a direct appropriation, to ensure its independence, and that it have the right to hire its staff. With the right combination of membership and mandate, the director may well be as fortunate as I was in bringing highly qualified experts to the staff for one- and two-year stints. I believe this had several beneficial results: it accelerated the Commission's work, because of their knowledge of their fields; it enhanced to the quality of the work (not the least because these staff wanted to produce intellectually respectable products of which they could be proud after they returned home); and it helped to avoid bureaucratization of the Commission because the principal staff members knew they were only going to be there for a limited time and had no incentive to build empires or establish cumbersome processes for the sake of power and control.

Plainly, there is much more that could be said about "doing ethics in public" through a federal commission charged to report on the ethical, social, and legal implications of biomedical and behavioral research and practices. I appreciate the opportunity to share these observations with your Committee, and I would be pleased to respond to any questions that you may have.

The CHAIRMAN. Do you favor limiting the general areas and topics that a commission would study and then give them some flexibility to get into other areas that they feel need to be addressed? Would this help insulate the commission from political interference?

Mr. CAPRON. The President's Commission had insulation in the sense that Congress itself could not make requests, and I know that that was a debated issue as you drafted that bill in 1978. I think in the long run it was a useful insulation.

On the other hand, the commission could take up topics. So if something were of great concern to Congress, the commission could not be mandated to do so, but could agree to take on the topic.

Giving an initial list I think is important, for two reasons: One, there will be things which I assume would be in the committee's mind and the Senate and House's mind in mandating such a commission. If you did not have anything you wanted a report on, why would you start it? I think the notion that there are just some issues out there is not enough. Second, as the commission first gets together, it is helpful for that group to have its marching orders.

But as we discovered, we were given several topics: access to health care, definition of death, and informed consent. And as we looked at the way those came together, we realized there was a very important topic about life-sustaining treatment, because it was the patients who were dead, according to the definition of death, but who got a lot of resources, which was a concern in the access issue, and where the decisionmaking process, as they moved out of the picture and as someone else had to decide, became very important. So we put those three together and created this additional topic for ourselves, and as I say, I think that became the report which is most often associated with the work of the President's Commission and has been very widely used and influential in States in adopting—almost all States now have the legislation we recommended there, and many, many courts have used it.

So I think that kind of flexibility, initial marching orders and then the ability to add additional topics, is highly desirable.

The CHAIRMAN. Do you think there is pretty broad agreement on what those initial marching orders might be? Is it possible to cover some areas of real significance and importance without pressing some hot buttons?

Mr. CAPRON. Obviously, the hottest button that gets pressed is the issue of abortion, and that was the rock on which the Biomedical Ethics Board foundered.

The experience of the National Commission, which as you recall from your floor discussion with Senator Buckley over the fetal research that was causing such concern and then the agreement that there would be a moratorium on that research, and you gave the National Commission 4 months to come up with a report on that, that Commission managed to come up with a very useful report on that topic, in part by clarifying the facts which had been greatly confused and exaggerated, and showing what it meant to conduct fetal research. A lot of it, obviously, was not on fetuses as such at all. It was on tissue and so forth.

So I think that that Commission indicates that it is even possible in these areas having to do with reproduction and abortion for a group to reason together. Frankly, we at the Biomedical Ethics Advisory Committee I think were on our way to some success there. I will take just a moment to tell you.

We had three topics that you had given us: one was fetal research; the other was more about life-sustaining treatment; and the third was the genetics issue. We chose to address genetics first because my sense as the Chair of that group—and I think other people around the table, members of that Advisory Committee, would have agreed—was that we came to that subject with much less of a preconceived set of notions. And I had the sense that if we could successfully work on that topic together, that out of that working together we could develop some confidence in listening to each other, and then we could go on to that fetal research issue with a little more reason and a little less heat in the process.

We never got the chance to do that because after our second meeting, when the Biomedical Ethics Board could not choose a new Chair and our funds were frozen and we did not have our 14th member, since one of the members had died, like a little embryo we were put in the deep freeze for 2 years, and then I guess they took us out and let us expire.

The CHAIRMAN. Just generally on the numbers, you want enough people on there to reflect diversity but at the same time I think most of us who work with various committees understand that there is sort of a magic number I feel, around 11, 12, 13. If it gets any bigger than that, you lose the construct of it, and if it gets smaller, you do not have the reflection. Do you agree?

Mr. CAPRON. Exactly my sense.

The CHAIRMAN. That is good. OK. Well, that is very helpful.

Have you looked into this whole question about the patenting of the human gene? Have you gotten into that? This is an area of particular interest.

Mr. CAPRON. I have not gotten deeply into that area personally as of now. I have been very interested by the debates at NIH, and, of course, Jim Watson basically leaving that position at the genome office because of his displeasure with the decisions that were being made by Dr. Healy to allow that patenting to go forward. But that is an example of where before one reached an ethical judgment, a lot of technical issues would have to be, in my mind, clarified.

The CHAIRMAN. OK. I know you have to go.

Mr. CAPRON. I will be happy to wait for as long as it seems reasonable to get my flight in case there is any further participation. Thank you.

The CHAIRMAN. Fine. We are going to move ahead. We have a full plate of activities for this committee from the President's Health Security Act to education reform. I am very hopeful that we will be able to move on this area. We have some important bipartisan support, and I think this hearing will be particularly helpful and useful to us.

Dr. Tolle, we are glad to have you.

Dr. TOLLE. Thank you. I welcome the opportunity to follow Professor Capron because I think my work as a clinical ethicist, as a practicing physician and ethicist, complement what he shares. In the hands-on, direct patient care, talking about the application of some of the challenges we face, I will focus much more on the clinical side because my expertise is greater there, but work through the fact that there really are two major branches in ethics: those who focus on research questions and those who spend more time in the patient care areas, the direct, hands-on application to issues that either affect the doctor-patient relationship or the broader societal implications that come directly out of that. For example, issues of confidentiality in medical information, a clinical question, rapidly arise as new technology develops, and soon we know so much about everyone and what has happened, and with genetic engineering what conditions you are likely to develop in the future. And how do we handle that confidential information?

In research, to show that side, the challenges of how do we handle studies of people with Alzheimer's that are advanced, who cannot choose, or those with advanced mental illness. How do we conduct very much needed research studies? But yet these are vulnerable people who cannot choose for themselves to willingly participate.

Again, on the clinical side, we can do so much that we sometimes wonder what to do with our technology. For example, we can keep people alive in permanent coma for over 3 decades. Should we?

At present, we have no formal body to help us bring together these questions, and I would like to focus a bit more on the clinical side by sharing two cases and some of the challenges they specifically pose for us in Oregon under the Oregon plan.

One is the kind of case that is sensational, that many people have heard about in the ICU, and the other, far more common but rarely being evaluated by the news media, that all of us in practice face every day.

The first case involves a 57-year-old woman. She has widely metastatic cancer. She has had three rounds of chemotherapy and now has cancer that is beginning to block her airway, beginning to block her kidneys, and involves the lining around her heart. Her doctors expect that she will live a couple of days.

If she has surgery around her heart, is put on a ventilator, and receives dialysis, she will probably live a couple of weeks in an intensive care unit. Under the Oregon plan, she would receive all measures to assure her comfort, and that would be supported by the State.

The State would not support the intensive care unit aggressive approach which would sustain her life for a couple of weeks, and not only that, but liability for the physicians and institution who did not provide it is clearly stated not liable.

In the current situation, when she says, "I understand that I may live just a couple more weeks, but I want it all," what do we do?

Well, as individual health care providers, when we look at the ethos of our profession, when we look at the national ethics codes, what we find is little guidance and lots of emphasis on the autonomy of individual patients. Individual patients get to make choices, and physicians are responsible for their relationship to an individual patient, without consideration to the implication for community and others.

Even so, even if we did not weigh in community, many times physicians feel very torn. They look at this person and feel that they are inflicting at times great suffering, let alone the economic issues, and wonder if they are doing the right thing. But, currently, national professional standards tell us that this woman has a right to demand this treatment and that by saying no, once we are well in the middle of our care—there are times when physicians say no to things they have not started, but this is an established relationship. This is with someone we already are caring for. And then to say no is much, much harder and less clear in the President's Commission and elsewhere in the professional standards.

The CHAIRMAN. Let me ask you, just the panel, about the number of medical schools now that have courses in bioethics. Is that part of their curriculum now, the required curriculum?

Dr. TOLLE. Yes.

The CHAIRMAN. All of them?

Dr. TOLLE. Nearly all.

Dr. RYAN. It is almost the same as every hospital having an ethics committee also. Ethics must be taught in medical schools.

Dr. TOLLE. But the degree of direct application varies enormously. Some speak mostly about principles and a more philosophical basis, and others are more directly applied. Some courses are elective, others required. So there is a lot of variability nationally on that question. But the national——

The CHAIRMAN. All of this comes down to the quality of care. I have seen it with regard to a variety of different circumstances involving my own family. So much depends upon the care of medical professionals.

Dr. TOLLE. Yes.

The CHAIRMAN. And how they are reacting or responding.

Dr. TOLLE. Absolutely.

The CHAIRMAN. I think most of us would agree that the people that are closest to the individual who is affected are the immediate family members, the people who love. There is an entirely different set of circumstances for a young mother that may be afflicted with cancer and has 3 children and something to live importantly for and somebody who is 70 years old and has had a full life.

Let me just ask you about whether you got into the questions of defining brain death and nonbrain death.

Mr. CAPRON. Yes. The President's Commission at the request of Congress reported on that. That is uniform law now in every State.

The CHAIRMAN. All right.

Dr. TOLLE. Yes. Death is not an issue. If someone is truly brain dead, we tend not to have the same degree of difficulty as if someone is in permanent coma, where we have a lot more anguish about whether to continue life-sustaining treatment, particularly in the face of no known preference on the part of the patient.

The CHAIRMAN. Do any of the States have differing definitions of death?

Dr. RYAN. No. They are uniform now.

Mr. CAPRON. There is almost uniformity now, Senator. It is very close.

The CHAIRMAN. Good.

Mr. CAPRON. The statute recommended by the President's Commission is the prevailing one, and there are some minor variations.

The CHAIRMAN. Good.

Dr. TOLLE. Where we are much more hung up is on the issue of futile or near futile treatment. When someone demands themselves or the family demands that things continue, the President's Commission last stated continue to have conversations, but did not tell any of us who are currently practicing how to deal with the demand for a lot when very little will be accomplished, and how to ever weigh in society's obligation. So that is a huge challenge, and it is a box with a star in it that goes down to no answer for us in current practice. And in Oregon, with the Oregon plan, we are now feeling that squeeze of not having any national professional codes or behaviors at an ethics level or a professional level to say when you weigh in the community and you make some choices. And we can discuss what those choices are and the differences. I think it is the whole tools of how to make them rather than the individual cases that are a real challenge.

The more dramatic ones in the ICU are the ones that we hear about so much in the media, but it is key to realize that the day-to-day issues of patient care also have less dramatic issues that put us in an equal squeeze.

Let me share a second case. It is a 29-year-old man who had an on-the-job back injury a week ago, has been examined twice by his doctor, and has been found to have spasm in his back muscles but no other problem. He has had a CAT scan, and now he says, "I want to see a neurosurgeon, and I want a myelogram."

He sees his doctor again. There is no medical indication. He has no evidence of nerve problems. The CAT scan showed now nerve root impingement. There is no medical invocation for this, but he is demanding consultation that is not medically indicated.

Currently, professional codes say patients can demand consultation. That is obviously going to put us in some huge challenges in health care reform with people who are saying people cannot demand things that are not medically indicated.

How are we going to deal with those issues, and what body do we turn to to set national standards? We cannot establish this only in Oregon. It is not a local issue. It is a national professional standard in the profession.

The CHAIRMAN. You know, I will give you a case that actually involved my son, Patrick. He had back pains, and he had an MRI, and it did not show any kind of indication on it. And his blood was fine. Having had a bad back, I know a lot of good back doctors. And I could just tell from being with him when he would get this pain, intense pain would come on, that it was not psychosomatic.

He had it for about 3 or 4 months, and I took those X-rays and I went around to see a number of doctors and asked them to look at them. They could not find anything. And when he would go to a particular hospital down in Providence, they would say, "Well, you are just in here one of those kids from the colleges who want pain-killing drugs," you know, and all the rest of it on that part, discouraged him from getting any more.

Finally, he went for a swim in the pool and lost his balance and could hardly get out of the pool. So he was smart enough to go up to Massachusetts General Hospital where they put him through an MRI, and they ratcheted up the MRI two notches, and they found a tumor inside the spinal column and operated on him the next morning, 12 hours.

If that tumor had been left alone there for another 2 days, most of them think that he either would have been crippled or could have been even more serious than that.

When you are speaking on this question, all of us have seen enough circumstances where you say, well, that person is just—you know, enough is enough. And on the other hand, there are these other circumstances where there are real kinds of questions. He had gotten the MRI, but it had not been up high enough because most of the pain was low enough so they took what they thought was going to be a sufficiently good cross-section on that, and it just missed it by two vertebrae. Eventually, when the doctors saw him, you know, they did the whole scan on it. So these are tough kinds of issues and questions about what to do.

Dr. TOLLE. Absolutely. Now, I think it is key in the patient that I was sharing that he had had a clear on-the-job injury. It sets up a circumstance when someone has no clear reason for why they might have gotten symptomatology. I think your thinking has to be very different when there is not a clearly identified situation.

This person had paraspinus muscle spasm, so you could feel the pull in the musculature. So there is something you could see and feel and say you knew you were going in the right direction.

When there are mysteries, I think the doors have to be open to continue to examine people, and you are quite right that in this situation—and I certainly did not mean to imply that this man had things in his head. He had paraspinus muscle spasm just as someone might twist their ankle and have strain and spasm. But at the same time, for this man the neurosurgeon was not the right answer, and setting up a situation to say I am not going to refer you, I will continue to see you closely, if your clinical situation changes at all I will refer you promptly, the back-up, that does need to be there.

As we think about these questions and the broader questions in research, in clinical decisionmaking, we are asking the kinds of questions that Professor Capron brought up about who should be on the commission, how could it be composed, and recognizing that a commission best focused to answer research questions may not be best focused to answer clinical questions; that a group that is going to focus primarily on questions in research should certainly have a number of scientists. But a group answering clinical questions needs more clinicians.

A research group might report in to the NIH. The clinical body certainly should not report there, but perhaps more directly to the President. And you are right about the challenges in depoliticizing the group and the challenges in the composition of the group. I would argue that the group, in addition to needing people from a wide range of disciplines needs ethicists with both philosophical orientation and practical clinical orientation—theologians, nurses, and others, both genders, and people from a wide range of ethnic and religious backgrounds to try to bring all of those perspectives in, and yet somehow as you are struggling, separate the direct political influence so that the group can take some heat.

Recently in Oregon, we have legislated some issues around pain management for dying persons. In November, it will be law that persons who have life support withheld or withdrawn must have adequate pain management given. It is not optional anymore. The law reads "shall provide medication to relieve pain and suffering."

Our Center for Ethics in Health Care helped the legislature design that, and then in the political heat, reference was made to us, allowing some things to go forward and some conversations about high-dose pain management that might shorten life and allowing some change to take place that really needed to take place. Can this national body similarly take some very tough issues, work on them in a way that is effective, and bring them back with thought to Congress for useful guidance and widely distribute them to set the professional standards that the medical schools can use in teaching the students and in setting policies and guiding their local ethics committees?

I welcome the opportunity to respond to questions.

The CHAIRMAN. Thank you very much. We will have some questions.

Dr. Ryan, we are glad to have a chance to hear from you again, and it is nice to see you.

Dr. RYAN. Senator Kennedy, I have an interest in both human research and clinical issues. I chaired the National Commission from 1974 to 1978 and, with admiration, watched the President's Commission in its deliberations from 1979 to 1983. I think both of those Commissions are examples of government sponsorship of successful efforts for public debate and development of policy guided by considerations in the area of bioethics. I think the United States really led the world in that effort.

Now, forgive me if I reminisce a little bit because in the National Commission we did discuss the Ralph sisters and the whole question of applying ethical principles to care provided in Medicaid and Medicare, for example, and the CIA and the FDA. I think the National Commission provided two contributions. One was the Belmont report, which were the principles which should underlie the conduct of research, and with a little imagination, they apply equally well to the practice of medicine. So there is a relationship between people doing research on human subjects and physicians caring for patients. There is that link.

I think the President's Commission and its contributions Alex adequately enunciated, but I feel that these commissions should be models for any future Government initiative in the creation of public bodies to consider bioethics. I think they seem to have worked, and I think that we should learn from their experience.

I want to say a little bit about the Ethics Advisory Board because I believe there was confusion in many people's minds about what the Ethics Advisory Board should do, and it builds on what Susan was talking about. The Ethics Advisory Board was formed in 1978 on the recommendation of our National Commission, and what we felt was that there should be a sitting body advising the NIH and the Secretary—then it was Health, Education, and Welfare rather than Health and Human Services—but to advise them——

The CHAIRMAN. Was that Joe Califano?

Dr. RYAN. Califano, right. To advise them in a continuing way on research issues that could not be adequately developed by local IRB's. The Oregon people might want advice, or the people in Massachusetts might want advice. We felt that there ought to be an ethics advisory board that worked.

Now, unfortunately, that board did not have a congressional mandate. It had a short life, only 2 years. They, in fact, considered in vitro fertilization and made recommendations which were never followed because there was no enabling clause in their creation. And you know what happened. Assisted reproduction was done in other parts of the world, and then it crept into medical practice in the United States without being preceded by federally funded research that would have ensured that some of the ethical concerns were being addressed. So I have often referred to that as a moral vacuum, the fact that we did not have any guidance in that particular area.

Now, I think we still need an ethics advisory board, and I believe it ought to have a congressional mandate, and it ought to have some kind of a clause to force consideration, not necessarily to agree with their recommendations but to force considerations in a public way in the Federal Register, for instance, the way the National and the President's Commission did.

I think we need an ethics advisory board to look at such things as: What are we going to do about the AIDS vaccines? Who is going to be tested? How are we going to be able to do that? Can we do that ethically on human subjects? Such questions as research on fertilized eggs and embryos. And lest people misunderstand, we are doing clinical practice on fetuses and embryos now and in vitro fertilization and assisted reproduction. So there is no question that someone has to ask serious questions about are we doing the right things and can we study it adequately.

Finally, the whole question of human genetic study, specific human genetic studies are going to come up that involve human subjects—gene therapy, for example—that a sitting body should be available to advise the Secretary of Health and Human Services.

Now, I want to shift, then, from that ethics advisory board, which I feel is needed and is discrete from the whole question of the initiatives that are needed in terms of a public body, discuss the things that are going to come up during the health care reform debate, the whole question of rationing of health services, of establishing a minimal level of health care, the use of genetic information, in all of these things a Presidential commission could be of vast service in the ethical debate that must be held so that we can have a public policy that does justice to our diverse society.

There are going to be all sorts of points of view on many of these issues, and there ought to be some kind of debate, a little outside of the political arena first if at all possible. And I think that is what a President's commission can do.

I think for it to succeed there has to be a congressional consensus that this kind of a body makes sense. I think you had that with the National Commission and with the President's Commission. There were specific agendas, and I agree with yourself and with Alex that there ought to be a specific agenda without too much interference in pursuing that agenda, but with the opportunity to look at new challenges.

You know, they asked us, unfortunately, to look at the swine flu vaccine problem which had come up, and no one really anticipated that that would be a problem. But we were a sitting body at the time.

I think the commission members should be of diverse background and experienced in scholarly or professional pursuits. I think if you get people with experience in this kind of discussion and people who are experienced in public service, they can rise above politics. I have infinite faith in the process. If you will leave them alone in a room and hold them to standards of decent discourse, I really believe that you can come up with valuable discussion. You may not always have people agreeing about these issues, but it is the discussion that is important. And what has happened in this country has been we have had a failure in the public debate. People are shouting at one another. There is a tremendous amount of rhetoric that goes on. Rather than saying someone has a right to this or someone has a right to that, we should say, well, let's talk about it. I think that has been possible in these commissions in the past, and I have faith that it is possible in the future.

They need the support of an adequate staff. I think the National Commission staff was superb. The President's Commission staff was superb. We held public hearings. We got public input. We operated under the sunshine laws.

Now, Dr. Nishimi was talking about the New York State task force, which I respect their writings. They are very, very good. It operates in closed sessions. I do not think the American public would sit still for that. They want to know what people are talking about and how they came to the decisions. And the National Commission operated under the sunshine laws, and a lot of people said it could not be done, that you could not talk about ethics. But once the television cameras went away and the commissioners sat around the table, they could start engaging in meaningful discussion.

Finally, I think that the enabling clause that you had the wisdom to write in, which requires that some Federal agent has to respond to the recommendations or public State why they will not respond, that gave us the courage. We worked hard as a public group, and that gave us the incentive to work hard because we knew people would take us seriously. I think that that was very, very important.

The CHAIRMAN. That came from the U.K. When they appoint a commission, there has to be a response. The Government either has to accept it or file reasons in the Parliament why they do not. We do not do that in this country, and we have a closetful of various commissions that have been focused on difficult problems, and there is virtually no kind of response. That was something that I noted. I was the chairman of the Administrative Practices Committee and used to follow these various commissions. That way of requiring action was enormously useful, or getting the reasons why they should not do it. I am glad you mentioned that because I had not remembered.

Dr. RYAN. I have just one or two further statements to make and would be happy to answer questions.

I think many—and it has been alluded to here—believe that our ethical debates have become too politicized, but we live in a political world. There is no question about that. And I think that the experience on the panel on fetal transplantation research was a difficult one for all of us, but I think if we had enough time, even on that panel, there would have been a different outcome because people who——

The CHAIRMAN. Well, the advisory committees that were set up I thought did well. It was just an override by the political figures.

Dr. RYAN. But it was a tough panel. But in spite of that, I still think that with careful selection of participants, effective review of ethical issues is possible. And I think it is crucial—not only possible, it is crucial—to both the Congress and the public with the health care things.

I want to finish by just again stressing the difference between an ethics advisory board that advises on ongoing research projects and things as they come up, and a public Presidential commission that would be involved more with policy and recommendations. I think there is a need for both of them, and they have different roles to play. And I would hate to see the two issues be confused.

I think I will stop there.

The CHAIRMAN. That is very good.

[The prepared statement of Dr. Ryan follows:]

### PREPARED STATEMENT OF DR. RYAN

The National Commission for the Protection of Human Subjects of biomedical and Behavioral Research which operated from 1974 to 1978 and the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research which operated from 1979 to 1983 are examples of government sponsorship of successful efforts for public debate and development of policy guided by considerations from the area of biomedical ethics. The National Commission contributed its "Belmont Report", the ethical principles which should underlie all human research and also contributed many reports and recommendations that were translated into government regulations to protect hyman subjects of a wide variety of federally funded research.

The Presidents Commission contributed to the standardization of criteria for brain death and made important contributions to considerations of forgoing life-sustaining treatment, DNA and genetics research policy as well as the ethics of the practice of medicine. These commissions should be models for any future government initiatives in the creation of public bodies to consider ethical issues.

An Ethics Advisory Board was formed in 1978 on the recommendation of the National Commission to advise the Secretary of the then Department of Health, Education and Welfare on controversial issues that might arise in human subject research as well as on the special topic of in vitro fertilization. Unfortunately, the Ethics Advisory Board had a short life of only 2 years and limited effectiveness. Absence of the Board effectively thwarted review of any research associated with the then burgeoning field of assisted reproduction. As a consequence, the United States lagged other countries in this field and in vitro fertilization was introduced into medical practice without the safeguards of prior carefully conducted federally funded research. The Ethics Advisory Board lacked a specific congressional mandate and a clause to force consideration of its recommendations.

I believe we still need an Ethics Advisory Board for ongoing review of ethical issues in the vast federally funded research programs including such issues as the development of a vaccine for AIDS, research on fertilized eggs and embryos, and human genetics studies.

With the current initiatives in health care reform and concerns about rationing of health services and the use of genetic information, a Presidential Commission could be of service in the ethical debates that must be held to develop a public policy that does justice to our diverse society. We should be mindful of those factors which seemed to work in the National and first President's Commissions. There was a congressional consensus on the need for such a body. There were specific agendas and adequate support. The Commission members were of diverse background but experienced in scholarly or professional pursuits and public service. They had the resources of excellent staffs to do the necessary fact finding, accumulation of data and organization of public hearings. The forcing clause in the legislation was of crucial importance in insuring a response to any recommendation either by complying or by publicly justifying an alternative course of action.

While many believe that our ethical debates have become too politicized as the experience with the Panel on Fetal Transplantation Research, I still believe that with proper time and careful selection of participants, effective review of ethical issues is possible and indeed crucial to both the Congress and the public at large.

The CHAIRMAN. Let me ask both of you, in our current reauthorization of NIH, a provision was included that allows the Secretary to establish an ethics advisory board to review any grant proposal on ethics grounds. In addition to this provision, do you think any further ethical body is necessary at NIH?

Dr. RYAN. No, but I think one should look carefully at how that ethics advisory board is set up so that the Secretary cannot ignore them, because that is Congress' and the public's window on what is going on in a very, very important area. And if you have that, then you do not have these terrible surprises which we had in the past.

The CHAIRMAN. Dr. Tolle, you mentioned the need for two commissions, one for clinical ethics and one for more broad-based research issues. Is Dr. Ryan adding another for policy recommendations?

Dr. RYAN. No.

The CHAIRMAN. Do you people agree on the division?

Dr. TOLLE. I think we do.

Dr. RYAN. If there is an ethics advisory board sitting and available to do what has to be done, we think that that will serve an important needs that has been missing. The other body for the clinical subjects that she has referred to is terribly important, and I do not see how we can go on with the health care reform without having some kind of a body sitting off on one side.

I know there were ethicists advising the executive branch on some of these ethical issues that are going to come up when you start talking about some control of the health care system.

The CHAIRMAN. We have been working closely with the various task forces, and I am not sure that this is an area that has been given all the attention it deserves. We have a group of health care professionals up in Massachusetts that are helping me, and I have some that are working on the ethical issues. They had been involved in the recommendations, but they have alerted me to give that more attention. We will try to in the time that remains prior to the President's submission of the program.

I will ask both of you this: What do you think are the basic, the most obvious ethical issues that we ought to be looking at, the types of things you think, in the health security legislation?

Dr. TOLLE. First, I want to answer a little more fully the question before this about the ad hoc body. I am concerned that the current mechanism is entirely inadequate in research and that even an ad hoc approach to proposals probably does not meet the need, that there probably does need to be something better, much more structured in research. The OTA report gave a more in-depth look at that, and I think it is extremely important. It is not where my greatest skills are in the area of research, but I am concerned that it, too, it was too atrophic as it is now.

With regard to the clinical side, where I can speak with more enthusiasm and experience, I am very concerned that in health care reform, what is happening to relationships with patients and the impact of managed competition needs careful attention and thought and review so that in management everything is not driven by cost, that there are other issues of quality and certain allegiances. Because when we start wearing two hats as physicians instead of one just to the patient, we need to know how to wear those appropriately. That just has not been thought through. I think that is extremely pressing, and many of us feel very torn every day. Who are we serving? And how quickly do we refuse that second further evaluation when it is not appropriate? As you are saying, for the back pain, there comes a point where you stop saying no and you say, no, I need to advocate for this patient. It has not been 1 week after a back injury. It has been 4 weeks, and I had no explanation in the first place, and further investigation is needed. How can we keep pushing the system?

So I think that is extremely pressing. Society, as we look at managed care, is also pressing on the issue: What are your personal obligations to your own health? How are we going to look at issues of the things that an individual contributes adversely to their own health and weigh that in in any way?

That has not been addressed at national standards, but it is a pressing question, and we have not looked at it. We do not want it to come down and be social worth. I am really saying that you deliberately neglect obvious things you could do for your health. Do you have any obligation to yourself? Do you miss any opportunities because of that? We need to struggle with some of those questions.

Obviously, AIDS is a huge issue, and HIV-infected persons, duty to treat, other obligations to care for them, confidentiality, a whole array of issues related to vaccine and other experimentation regarding the care of HIV-infected persons, confidentiality. We are really challenged with the whole issue of confidentiality. Does it really exist in medical practice? Not in the way it used to when so many people can fairly quickly call up on the computer someone's lab tests, can fairly quickly look at so much scanned in your bill files about whether or not you have seen counseling, all kinds of information that we are struggling within this technological age, what to do with confidential medical information. So many, many things are pressing on us.

Dr. RYAN. Of course, the most fundamental issue, the most fundamental ethical issue for us in health care is access of our citizens. And the disgrace has been that we have not had universal entitlement of a minimal standard of health care.

That seems to be the wave of the future, that the Congress is probably going to do something about that. But it is the question of time, how long is it going to take, and what are the trade-offs that are going to be made in terms of setting that minimal standard of care that we can afford or think we can afford versus what we ought to do.

So I think that one of the real challenges for this country vis-a-vis the rest of the developed world was really getting health care for all of our citizens. Now that we have committed ourselves to doing that, the whole question is the time, the pace, how we are going to do it, and how these are going to be set up.

It is very easy to promise that everyone will have freedom of choice, but I, working in the health care field, as you know, feel very, very strongly that that is a false promise; that there is no way that citizens in this country can have universal entitlement and free choice of their physicians. They are going to have to make choices and trade-offs in order to get that.

So some of the rhetoric that goes on about the health care issues already I think is in the area of false promises. Question of access, of minimal level of care, the questions that have been raised about how much economics will drive the system, I think are tremendously important.

If you watch the international newspapers, you will notice that in England physicians are refusing to do surgery, heart surgery on gentlemen who smoke if they will not give up smoking, for example. You were really talking about something like that. How much responsibility do we have for our own health care and are we going to punish people? It is the whole question of do you give a liver to someone who is an alcoholic, who is addicted to alcohol, for example?

I think there are very, very profound ethical issues about that. The whole question of who gets a heart when not everyone can get one, and it all started with the renal dialysis in Washington, as you know, when they had that death committee. We do not do well with those committees that try to decide between the worth of people, who is going to get health care and who is not going to get health care.

So I think if I were going to create a list, if you will, of issues, I think the whole question of rationing, of access to health care, the minimal level of health care, these are the kinds of things that have to be thought out from an ethical perspective.

The CHAIRMAN. Of course, it is a myth that currently all people—have choice. The 40 million people who do not have any health care, do not have any choice. And by and large, the employers are making the decision. The employees do not have much of a choice, you know, the requirements that they offer, an HMO or whatever. We all want as much choice as we can possibly have, and I think the way that this is shaped and fashioned will give a great deal more than they ever have now. Now the number of people who have real choice are very, very few, and they are usually the ones that have the greatest resources.

Dr. RYAN. I have just been to Canada, and I have been to England recently, and all I can tell you is both of those systems are hurting for resources. Health care costs money, and they have had to make choices.

I know in England, for instance, there are a lot of centers that will not pay for assisted reproduction, for example. And I think that Oregon may very well have to make those kinds of decisions. But even those systems which are held up as ones that have provided universal entitlement, they are really feeling it now because they are having to close hospitals or merge hospitals and restrict services because of the whole question of resources.

It is an ethical decision how much we as a nation spend on this versus other things that are terribly important to us.

The CHAIRMAN. Yes, as compared to education.

Dr. RYAN. Yes.

The CHAIRMAN. The amounts that we are spending, the Federal Government, on health as compared to education, let alone the primary. We spend somewhere about $10 or $11 billion a year on 43 million school children, and we are spending about $350 billion a year on health care in Medicaid and Medicare.

Dr. RYAN. I am very excited about the possibility of moving the health care of children into the schools, and I think people are looking at that.

The CHAIRMAN. That is right. I think those school clinics are just indispensable. Cambridge Ringe and Latin has an excellent program up in my home State of Massachusetts, which has a tremendous impact on the health of the kids. The best estimate is that about 30 percent of the kids in the inner city need some kind of health assistance, whether it is trying to help them in terms of living in a home where there is substance or physical abuse or whether there are other kinds of problems dealing with their mental conditions or ingesting lead paint poisoning. We all know that these problems exist—and in many ways we have failed to properly address them.

I will make a serious effort to try and have a careful review of what the administration is proposing on these ethical issues, and I may call on you for further assistance as we begin to address some of those questions.

I want to thank you very much. It has been an enormously interesting hearing. Your insights will help us to address the fundamental questions which advancements in science raise each day.

We thank you very much, and the committee stands in recess.

[Additional statements and material submitted for the record follow:]

United States Senate
DAVE DURENBERGER

October 14, 1993

The Honorable Nancy L. Kassebaum
Committee on Labor and Human Resources
United States Senate
Washington, D.C. 20510

Dear Nancy:

I am sorry that I am unable to attend today's hearing due to a death in my family. I would be very grateful if you would extend my apologies to our colleagues and especially to Mike Peel, Senior Vice President of Personnel for General Mills, who will be here from Minnesota to testify today.

I would also be grateful if you could ask that my formal statement be submitted for the record.

Sincerely,

Dave Durenberger
United States Senate

Senator Durenberger wanted me to pass on his deepest apologies to the Committee and to the witnesses. Unfortunately, due to a death in his family, he is in Minnesota attending a funeral this morning and is unable to attend today's hearing.

He asks permission that his statement be made part of the record.

And he wanted me to make sure that his absence was not in any way interpreted as a lack of interest, nor a lack of respect for the critical role that both employers and employees will play in shaping our nation's future health care system.

He especially wanted me to extend his apologies to Mike Peel, Senior Vice President of Personnel for General Mills, who is here from Minnesota to testify today. Senator Durenberger has spoken very highly of you, your knowledge of this issue, General Mills' concern for its employees, and the contributions that you and your company bring to this debate.

[Editor's Note--At press time, Senator Durenberger did not supply a prepared statement]

# TESTIMONY ON A STANDING ETHICAL ADVISORY BOARD AND A NATIONAL BIOETHICS COMMISSION SUBMITTED TO THE LABOR AND HUMAN RESOURCES COMMITTEE

As members of the Senate Labor and Human Resources Committee consider the question of how best to address ethical issues in medicine, the committee should be aware of the work of the National Advisory Board on Ethics in Reproduction (NABER). NABER is an independent, non-partisan body of professionals in medicine, reproductive sciences, bioethics, and the law. It was established in 1991 to develop reports and guidelines on ethical and policy issues that arise in the development and application of new reproductive technologies, fetal research, and fetal tissue use. The board consists of 14 volunteers who have nationally recognized expertise in bioethics, bioscience, medicine, law and policy, assisted by a Consultants' Working Group of 18. Originated by support from the American College of Obstetricians and Gynecologists and the American Fertility Society, NABER is now funded by grants from leading foundations (Ford, Greenwall, Walter and Elise Haas, Josiah Macy, Jr., and Rockefeller) and is a separately incorporated legal entity with 501 (c) (3) status. Thus, NABER is the private sector equivalent of the sort of governmental bodies presently being considered by this committee.

NABER came into existence because of the conviction of several leading figures in reproductive science and in bioethics that governmental entities would be unlikely to provide the guidance, oversight, or leadership necessary in the highly sensitive and seriously politicized area of reproductive science and technology. The history of the DHEW Ethics Advisory Board, the Fetal Tissue Panel, and the Congressional Biomedical Ethics Board provided ample evidence to support their conviction. The conspicuous success of the two early congressional commissions, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and the President's Commission for the Study of Ethical Problems in Medicine, on both of which NABER's chairman served, was due to their insulation from partisan pressure and from the influence of special interests. This may no longer be possible, particularly in the sensitive area of human reproduction. Even if future governmentally established bodies in bioethics can be so insulated, the ethics of human reproduction and the reproductive sciences will probably remain vulnerable to such pressures and influences. At the same time, the public and professionals need information, analysis and guidance in this rapidly developing science and its clinical utilization. The public moral debate that attends every innovation -- in vitro fertilization, prenatal diagnosis, surrogacy, ovum transfer -- should be focused, analyzed and translated into reasonable recommendations that professionals, the public, and policy makers can respect. This is NABER's purpose.

At present the Board selects those issues that seem to require immediate and intense ethical scrutiny. It does so on its own initiative, on advice of its consultants, and on recommendations from interested professionals. It has produced one report on the therapeutic use of fetal tissue, is now preparing a report on oocyte donation and intends to study fetal cell sorting. It has offered its expertise in reproductive ethics to N.I.H. for review of protocols in reproductive science that raise ethical issues. It may extend this offer to the research community at large.

If an Ethical Advisory Board is reestablished under governmental auspices, NABER would be able to provide the input that its concentrated expertise makes possible. If a permanent commission were established NABER could, at the request of the commission, do specialized studies that would benefit both from the diversified views of its bioethics and legal scholars and the skill of its scientists, but would be free of partisanship and partiality. NABER would certainly be willing to collaborate with any governmentally established body. If no such body is forthcoming, NABER will continue to provide soundly researched impartial opinion on biomedical policy in human reproductive science and medicine.

## Appendix A

## MEMBERS OF THE NATIONAL ADVISORY BOARD ON ETHICS IN REPRODUCTION (NABER)

Albert R. Jonsen, Ph.D., Chair, Medical History and Ethics, University of Washington, Seattle, Washington, Chair of NABER

Ruth Macklin, Ph.D., Epidemiology and Social Medicine, Albert Einstein College of Medicine, Bronx, New York, Vice-Chair of NABER

Ezra C. Davidson, M.D., Obstetrics and Gynecology, King-Drew Medical Center, Los Angeles, California, Secretary/Treasurer of NABER

Lisa Sowle Cahill, Ph.D., Theology, Boston College, Chestnut Hill, Massachusetts

Thomas E. Elkins, M.D., Obstetrics and Gynecology, Louisiana State University, New Orleans, Louisiana

Clifford Grobstein, Ph.D., Science, Technology and Public Affairs, University of California School of Medicine, San Diego, La Jolla, California

John S. Hoff, J.D., Law, Swidler and Berlin, Washington, D.C.

Patricia King, J.D., Law, Georgetown University, Washington, D.C.

Mary Martin, M.D., Reproductive Endocrinology, University of California School of Medicine, San Francisco, California

Paul McDonough, M.D., Reproductive Endocrinology and Genetics, Medical College of Georgia, Augusta, Georgia

Mildred T. Stahlman, M.D., Pediatrics and Pathology, Vanderbilt University School of Medicine, Nashville, Tennessee

Moses Tendler, Ph.D., Biology, Talmudic Law, and Jewish Medical Ethics, Yeshiva University, New York, New York

Allen Verhey, Ph.D., Director, Institute of Religion, Texas Medical Center, Houston, Texas

Walter J. Wadlington, L.L.B., Law, University of Virginia School of Law, Charlottesville, Virginia

Cynthia B. Cohen, Ph.D., J.D., Executive Director

## Appendix B

## CONSULTANTS' WORKING GROUP OF THE NATIONAL ADVISORY BOARD ON ETHICS IN REPRODUCTION (NABER)

Anita Allen, J.D., Ph.D., Law, Georgetown University, Washington, D.C.

Judith L. Benkendorf, M.S. Genetic Counseling, Georgetown University Medical Center, Washington, D.C.

Dan Brock, Ph.D., Philosophy, Brown University, Providence, Rhode Island

Ruth E. Bulger, Ph.D., Director, Health Sciences Policy, Institute of Medicine, National Academy of Sciences, Washington, D.C.

Alta Charo, J.D., Law and Medical Ethics, University of Wisconsin, Madison, Wisconsin

Sherman Elias, M.D., Reproductive Genetics, Obstetrics and Gynecology, and Genetics, University of Tennessee College of Medicine, Memphis, Tennessee

Elizabeth Heitman, Ph.D., Public Health, University of Texas, Houston, Texas

Howard Jones, M.D., Obstetrics and Gynecology, Eastern Virginia University, Virginia

Carol Levine, M.A., Executive Director, The Orphan Project, New York, New York

Richard McCormick, S.J., Theology, Notre Dame University, South Bend, Indiana

Nancy Press, Ph.D., Anthropology, Psychiatry and Biobehavioral Sciences, University of California at Los Angeles, Los Angeles, California

John Robertson, J.D., Law, University of Texas, Austin, Texas

Kenneth Ryan, M.D., Obstetrics and Gynecology, Harvard University, Cambridge, Massachusetts

Bonnie Steinbock, Ph.D., Philosophy, State University of New York, Albany, New York

Carson Strong, Ph.D., Philosophy and Human Values in Medicine, University of Tennessee College of Medicine, Memphis, Tennessee

Rosemarie Tong, Ph.D., Medical Humanities, Davidson College, Davidson, North Carolina

Edward Wallach, M.D., Obstetrics and Gynecology, Johns Hopkins University, Baltimore, Maryland

LeRoy Walters, Ph.D., Religion, Kennedy Institute of Ethics, Georgetown University, Washington, D.C.

TIMES ■ TUESDAY, JULY 6, 1993 3A

## HEALTH & MEDICINE

# Board to consider reproduction ethics

By BRUCE HILTON
Scripps Howard News Service

Remember the divorced couple who sued each other for custody of seven tiny fertilized eggs they had created together?

Or the millionaire couple who disappeared at sea, leaving as their only "family" some frozen test-tube embryos in Australia?

Or the surrogate mother who said poverty had forced her to agree to bear a baby for a rich couple — and now she didn't want to give up the child?

Or the baby with five parents: the couple who would rear the child, the man who donated the sperm, the woman who donated the ova and the woman who gave it birth?

Or the prenatal test that makes it possible to tell whether it's a boy or a girl — and abort the fetus if it's the "wrong" sex?

It has been 15 years since the first test-tube baby. In that time, science has come up with a handful of other new reproductive technologies — and women have given birth to 23 000 babies as a direct result. It's no longer unusual to know somebody using one of these techniques, and no longer surprising when ethical problems pop up.

Now the good news:

The major foundations have financed a new, broad-based, non-sectarian group called the National Advisory Board on Ethics in Reproduction and taken on the job nobody has been able to handle so far.

Widely respected among ethicists, the 12 board members come from a variety of disciplines and backgrounds. They want to combine existing research and public discussion, hoping to come up with guidelines for a spectrum of new ways to have babies.

These are some of the ethics issues they're willing to take on, as outlined in their first report:

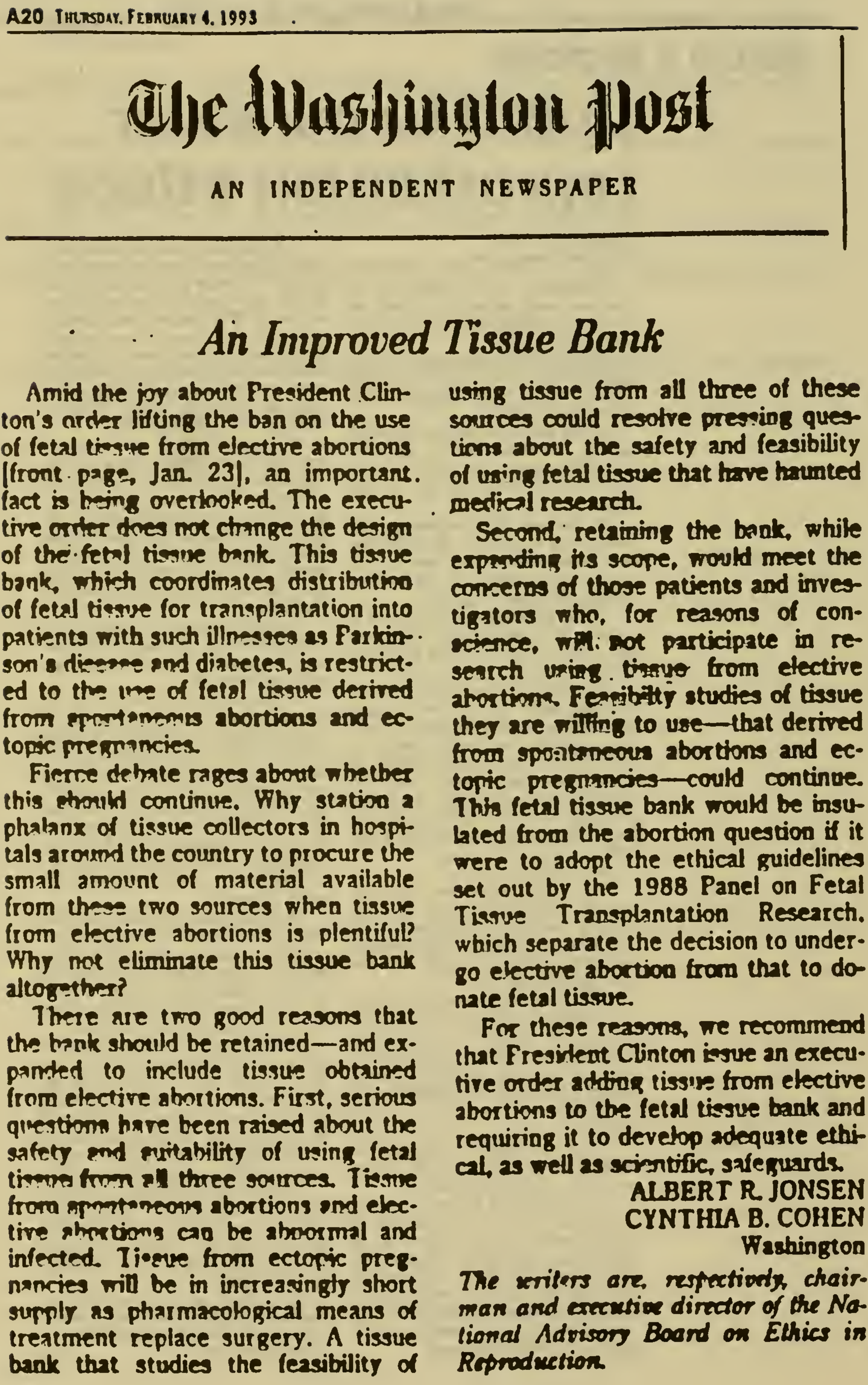
- **Control and access:** Does every couple have a right to have a family, using whatever means available? If so, is infertility an illness? Will government help those who can't afford the high costs? If not, will government enforce laws against it? Who should have access to genetic screening, and for what purposes?
- **Coercion and commercialism:** Will women's choices actually be lessened because of pressure to have babies, now that the new techniques are here? Will couples be forced to use prenatal diagnosis because of public censure if they have a disabled child? Will surrogate motherhood become not only a profession, but a new way of exploiting women? Will humans become commodities?
- **Genetics and the perfect person:** What genetic tests should be offered — or required? Who will decide what defects are serious enough to screen out? Shall industries use genetic information (like a predisposition to heart disease) to deny employment? Will widespread screening make us less tolerant of people with disabilities?

As the report says, some ask: "At what point does medical genetics become eugenics" (the search for genetic perfection)?

- **Parents and helpers:** Do test-tube babies and surrogate mothers strengthen the family, or threaten the whole idea? Who should have priority in a dispute, a birth mother or a genetic mother or the rearing mother? Will children suffer psychologically or physically because they're born of these techniques? Should donors be anonymous? Have male donors and female donors been treated with equal fairness?
- **Health-care professionals:** Many of the new techniques are not medically indicated — they don't cure an illness. Are physicians obligated to perform them? How should the powers and responsibilities of the patient and the professional be balanced?
- **Manipulating embryos:** Is the newly fertilized pre-embryo, microscopic in size, a human being? What limits should be set for creating, manipulating or experimenting with it? Amid rising health costs, should society demand that embryos carrying certain disorders be discarded?

If these issues affect you, or interest you, write for the first paper, "Issues We Face," at the National Advisory Board on Ethics in Reproduction, 409 12th St. SW, Washington DC 20024.

**— Bruce Hilton, director of the National Center for Bioethics, has been an ethics consultant to doctors, hospitals and patients for 19 years.**



A20 Thursday, February 4, 1993

The Washington Post

AN INDEPENDENT NEWSPAPER

## An Improved Tissue Bank

Amid the joy about President Clinton's order lifting the ban on the use of fetal tissue from elective abortions [front page, Jan. 23], an important fact is being overlooked. The executive order does not change the design of the fetal tissue bank. This tissue bank, which coordinates distribution of fetal tissue for transplantation into patients with such illnesses as Parkinson's disease and diabetes, is restricted to the use of fetal tissue derived from spontaneous abortions and ectopic pregnancies.

Fierce debate rages about whether this should continue. Why station a phalanx of tissue collectors in hospitals around the country to procure the small amount of material available from these two sources when tissue from elective abortions is plentiful? Why not eliminate this tissue bank altogether?

There are two good reasons that the bank should be retained—and expanded to include tissue obtained from elective abortions. First, serious questions have been raised about the safety and suitability of using fetal tissue from all three sources. Tissue from spontaneous abortions and elective abortions can be abnormal and infected. Tissue from ectopic pregnancies will be in increasingly short supply as pharmacological means of treatment replace surgery. A tissue bank that studies the feasibility of using tissue from all three of these sources could resolve pressing questions about the safety and feasibility of using fetal tissue that have haunted medical research.

Second, retaining the bank, while expanding its scope, would meet the concerns of those patients and investigators who, for reasons of conscience, will not participate in research using tissue from elective abortions. Feasibility studies of tissue they are willing to use—that derived from spontaneous abortions and ectopic pregnancies—could continue. This fetal tissue bank would be insulated from the abortion question if it were to adopt the ethical guidelines set out by the 1988 Panel on Fetal Tissue Transplantation Research, which separate the decision to undergo elective abortion from that to donate fetal tissue.

For these reasons, we recommend that President Clinton issue an executive order adding tissue from elective abortions to the fetal tissue bank and requiring it to develop adequate ethical, as well as scientific, safeguards.

ALBERT R. JONSEN
CYNTHIA B. COHEN
Washington

*The writers are, respectively, chairman and executive director of the National Advisory Board on Ethics in Reproduction.*

# BIOETHICS AND U.S. PUBLIC POLICY

Committee on Labor and Health Services

October 14, 1993

Susan W. Tolle, M.D.

Director, Center for Ethics in Health Care

Oregon Health Sciences University

Senator Kennedy and Members of the Committee:

I am Dr. Susan Tolle, a practicing internist and Director of the Center for Ethics in Health Care at the Oregon Health Sciences University. I completed my medical school training at the Oregon Health Sciences University and my residency in Internal Medicine at the University of California, San Diego. I joined the faculty in the Division of General Internal Medicine at the Oregon Health Sciences University in 1981 and am currently a Professor of Medicine at OHSU. In addition to my Internal Medicine training, I have received formal training in clinical medical ethics, completing a Fellowship at the University of Chicago prior to assuming the position of Director of the Center for Ethics in Health Care in 1989. My strengths are in the areas of clinical ethics as they relate to the provision of health care to individual patients and the implications of clinical care to broader social policy. I have less expertise in the area of ethical issues in research. In using the term, clinical ethics, throughout this document, I am referring to decisions made in health care settings that relate directly to the practice of medicine and the care of patients, whether at an individual level or a societal level, rather than to research ethics, which have been eloquently described in the OTA report.

I welcome the opportunity to talk with you about the impact of recent technological advances on long established traditions in health care which contribute to a rising number of unresolved dilemmas. What does confidentiality mean in the face of computerized patient data and rapidly growing, yet deeply personal, genetic information? How can we protect vulnerable persons and yet proceed with vital research studies of individuals with mental illness or dementia? Have research and health care technological advances outstripped our ability to use them wisely? We can now keep patients alive in permanent coma for more than three decades. The Federal government is currently without a formal forum to provide guidelines on these and other pressing bioethical issues.

1. **Should Congress provide voices for biomedical ethics in public policy?**

The need for a body to thoughtfully provide guidance on the ethical issues in research has been highlighted by the OTA report. I concur that Congress should establish an Ethics Advisory Board to provide national guidance about an array of pressing ethical issues in research. Of equal importance are dilemmas in clinical ethics which have received inadequate national guidance since 1983, when the President's Commission was disbanded. Changes in health care technology and practice necessitate reevaluation of obligations in the doctor-patient relationship by a national ethics commission. These profound, professional changes cannot be resolved at the state level. Thus, I believe Congress should establish two separate bodies: one to address research and the other to guide clinical issues in biomedical ethics and public policy.

2. **Can one national ethics body effectively address the full range of ethical issues?**

No. The array of issues in biomedical ethics have become far too broad for any individual to maintain expertise in all areas. Some biomedical ethicists have focused on ethical issues in research and others have greater knowledge about issues in clinical ethics (both at the individual patient and community levels). Research scientists are clearly needed on a board addressing questions in research, similarly, persons experienced in clinical care should be called upon to address the new array of clinical ethics dilemmas. A reporting relationship within the NIH may be appropriate for a research focused advisory body, but would make little sense for a clinically focused commission. Thus, the composition of the two boards or commissions and reporting relationships should be different.

3. **Is an ad hoc approach adequate to meet the needs?**

No. I concur with the OTA report that an ad hoc committee focused on a specific topic is the least desirable mechanism to address bioethical dilemmas. An ad hoc committee takes significant time to appoint and convene, and therefore cannot address issues or research protocols in a timely manner. Standing bodies or those with limited terms offer the opportunity for the benefit of experience, initial learning, and the acculturation process of any group to enhance the group's effectiveness.

**4. Pressing issues in clinical ethics.**

The OTA does a superb job of describing and delineating a wide range of ethical issues in research, but fails to probe many pressing issues in clinical ethics. The following cases demonstrate the type of ethical issues that were overlooked. These clinical dilemmas cannot be solved at the local hospital or State level, and require a national body to guide new standards in dealing with these clinical ethics dilemmas.

Case 1

*A 57 year-old woman has widely metastatic breast cancer. She was diagnosed four years ago, initially treated surgically, and subsequently, when metastatic cancer developed, she received three different courses of chemotherapy. She has now failed the third round of chemotherapy and has cancer widely spread throughout her bones and internal organs. She has cancer in her lungs which is beginning to cause her to be somewhat short of breath; she also has cancer which is beginning to block the outlet of her kidneys; and her doctors expect that she will not live more than a short period of time - a few days. Perhaps if she goes to the Intensive Care Unit and is put on a ventilator and receives dialysis, she might live as long as a few weeks. The patient demands all life extending measures given. She understands that all of these treatments will only extend her life a few weeks. She wishes surgery for a cancer around the lining of her heart, to be placed on a ventilator, and to receive dialysis, though she understands that even with all of these measures, her cancer will continue to grow and that she is not expected to live more than a month. Her doctors and the entire health care team are concerned that they may be increasing her suffering by providing all of these modalities. Despite feeling they were doing the wrong thing, the health care team complies with her wishes.*

Case 2

*A 29 year old man had an on the job injury a week ago. His doctor has examined him twice and a CAT scan has been done. He has acute muscle strain without any neurologic findings. The patient demands referral to a neurosurgeon and wants a myelogram performed. His primary physician reconfirms the lack of neurologic finding and believes there is* ***no*** *medical justification for the referral. His physician wonders what he should do in the face of national professional ethics codes which state that patients have the right to demand consultations.*

Traditionally, health care providers have seen their ethical obligation as related only to the advocacy of the individual patient, no matter how unlikely a medical treatment was to benefit the patient or how expensive, the physician was expected to advocate for the patient. National ethics standards and standards of professional organizations have endorsed this emphasis on individual patient autonomy without consideration of the broader needs of the community. The Oregon Plan and other efforts at managed competition have forced us to look more critically at treatment which is medically futile, very expensive and unlikely to be effective except for the briefest period of time. Under the Oregon Plan, the patient with end stage cancer would continue to receive state support for all measures which would enhance her comfort. However, she would not receive state reimbursement for care in an Intensive Care Unit with a ventilator and dialysis during her final weeks of dying from a cancer which is unresponsive to chemotherapy. Of note, the doctors and hospital would not be liable for declining to provide intensive care.

Not addressed by any of the efforts at health care reform is the traditional model of the individual physician-patient relationship and how it needs to be revised to incorporate the values and needs of the community as a whole. Can patients demand to be referred to a consultant even if medically there is no need? Does this violate the individual autonomy of the patient? While Case 1 portrays the issue of autonomy in an end of life situation, the issue demonstrated in Case 2 arises much more frequently and is an everyday occurrence in the outpatient setting.

New challenges in clinical ethics are not limited to individual autonomy versus the overall needs and interests of the community related to resource allocation, but extend to a range of issues, such as confidentiality of health care information in the computer age, duty to treat, personal responsibility for one's own health, issues around treatment of HIV infected persons. A national commission similar to the President's Commission is very much needed to address these patient care dilemmas. Because of the increasing integration of health care financing systems, revising professional relationships with patients to incorporate not only individual autonomy, but the overall wishes and needs of the entire communities we serve will require national rather than local leadership to address.

5. Goals in selecting board or commission members:

A range of perspectives is vital to assure that a broad and multifaceted view of the ethical question(s) is achieved. This necessitates assuring a range of disciplines which would include not only ethicists who are philosophically oriented, but also those who are clinically oriented, thus assuring a broad-based perspective and a hands-on applied perspective to complement multiple aspects of issues in both the research and clinical ethics commissions work. In addition to a range of disciplines, (physicians, nurses theologians, philosophers, etc.), clearly representation from both genders and a range of racial and ethnic groups is needed to assure the greatest possible vision.

I would be pleased to answer any questions you may have regarding bioethics and U.S. public policy and our national needs for two commissions - one to address ethical issues in research, and the other to address ethical issues in clinical ethics, both at the bedside and in broader social policy.

Thank you for the opportunity to discuss these issues with you.

[Whereupon, at 4:42 p.m., the committee was adjourned.]

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